QSOFA and SOFA scores are valuable tools for predicting postoperative sepsis resulting from ureteroscopic lithotripsy (URSL)

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Abstract
The sequential organ failure assessment (SOFA) and quick sequential organ failure assessment (qSOFA) scores are new tools which are used to assess sepsis based on the Third International Consensus Definitions for Sepsis and Septic Shock Task Force. This study aimed to evaluate the feasibility of using the SOFA and qSOFA to predict post-ureteroscopic lithotripsy (URSL) sepsis. Patients who underwent URSL due to ureteral stone obstruction were retrospectively reviewed using SOFA and qSOFA scores. Patient characteristics including age, gender, comorbidities, American Society of Anesthesiologists Classification, stone burden, stone location, hydronephrosis status, infectious status, preoperative SOFA and qSOFA score were collected. Preoperative factors were analyzed to determine if they were correlated with postoperative sepsis. A total of 830 patients were included in this study, of whom 32 (3.9%) had postoperative sepsis. Multivariate analysis revealed that older age, proximal ureteral stones, severe hydronephrosis, and high preoperative qSOFA or SOFA score were significantly associated with postoperative sepsis. The areas under the curves of a qSOFA score ≥ 1 and SOFA score ≥ 2 for predicting postoperative sepsis were 0.754 and 0.823, respectively. Preoperative qSOFA and SOFA scores are convenient and effective for predicting post-URSL sepsis. Further preventive strategies should be performed in these high-risk patients.

Abbreviations: AUC = area under the curve, DM = diabetes mellitus, ICU = intensive care unit, qSOFA = quick sequential organ failure assessment, ROC = receiver operating characteristic, SIRS = systemic inflammatory response syndrome, SOFA = sequential organ failure assessment, URSL = ureteroscopic lithotripsy.

Keywords: predicting, QSOFA, SOFA, URSL sepsis

1. Introduction
Ureteroscopic lithotripsy (URSL) is a commonly used tool for treating ureteral stones. Despite refinement of the instruments and surgical techniques infectious complications still occur, and given that it is an invasive procedure, some morbidities are inevitable. De la Rosette et al prospectively analyzed 11,885 patients who received URSL and found that the infection rate was 2.8%. The most serious infectious complication, sepsis, is a concern for all physicians because of its high morbidity and mortality. Sepsis is a systemic disease comprising physiological, pathological, and biochemical abnormalities. It used to be defined as a systemic inflammatory response to infection, and it could be diagnosed by meeting 2 or more systemic inflammatory response syndrome (SIRS) criteria, including tachycardia (heart rate > 90 beats/minute), tachypnea (respiratory rate > 20 breaths/minute), fever or hypothermia (temperature > 38°C or < 36°C), leukocytosis, leukopenia, or bandemia (white blood cells > 1200/mm³, <4000/mm³ or bandemia ≥ 10%).

How to predict and prevent postoperative sepsis is a very important clinical issue. He et al reported that the degree of preoperative hydronephrosis was related to postoperative sepsis. Another study reported that postoperative urinary tract infections and urosepsis in URSL were correlated with stone burden. However, the degree of hydronephrosis and stone burden are not currently standardized, and clinical physicians need a more objective and effective tool for predicting sepsis.

In 2016, the Society of Critical Care Medicine and the European Society of Intensive Care Medicine advocated that sepsis should be defined as a life-threatening organ dysfunction caused by a dysregulated host response to infection. The Sequential organ failure assessment (SOFA) score was then proposed as a new scoring system by the society of critical care
2. Materials and methods

The study protocol was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Review Board of China Medical University Hospital in Taiwan (IRB: CMUH109-REC1-079). Patient consent was waived, due to retrospective study and all data had been de-identified under review by the Institutional Review Board of China Medical University Hospital. A total of 862 patients who underwent URSL between 1 January, 2014 and 31 December, 2019 at our hospital, a tertiary referral center, due to obstructive ureteral stones were recruited. Thirty-two patients were excluded due to preoperative sepsis as defined by the SIRS criteria. We also excluded patients who had vesical or renal stones to minimize interference. Finally, 830 patients were enrolled in this study.

The URSL procedure involved placing the patients in the lithotomy position, and a hydrophilic guidewire was inserted through a 19F cystoscope. A 4F, 6F, or 8F semi-rigid ureteral scope (Richard Wolf, Germany) was then used to approach the stone. A pneumatic lithotripter (Swiss Lithoclast® – Electro Medical Systems) or holmium YAG laser was used to fragment the stone, and a 1.9F basket was used to extract the fragmented calculus. After the lithotripsy, 6F ureteral double-J stenting was placed in most of the patients for 4 to 90 days depending on the presence or absence of ureteral trauma. The surgeon decided on whether or not to place the ureteral double-J stenting depended on the state of the ureteral mucosa following lithotripsy. The operating time was calculated from insertion of the cystoscope to placement of the urethral catheter.

Variables of interest, including the patient’s gender, age, comorbidities (such as diabetes mellitus (DM) etc), American Society of Anesthesiologists Classification, stone burden, stone location, hydrenephrosis status, the pre- and postoperative SIRS, and sepsis patients. Several previous studies have demonstrated that changes in the SOFA or qSOFA score were good predictors of mortality or risk stratification in both intensive care unit (ICU) patients and sepsis patients. This study aimed to evaluate the feasibility of using SOFA and qSOFA scores for predicting post-URSL sepsis.

2.1. Definition of SOFA and qSOFA score

The SOFA score was evaluated using 6 important systems, including respiration (PaO2/FiO2), coagulation (platelet count), liver (bilirubin), cardiovascular (mean arterial pressure), central nervous system (Glasgow Coma Scale, GCS), and renal system (creatinine and/or urine output). A detailed definition of the SOFA criteria including the relevant thresholds is shown in Table 1. The qSOFA score evaluated systolic blood pressure (≥100 mm Hg), respiratory rate (≥22 breaths/minute) and altered mental status (GCS < 15).

2.2. Statistical analysis

Comparisons between predictive factors and outcomes were assessed using the chi-square test or Fisher’s exact test for categorical variables, and the Mann–Whitney test for continuous, normally distributed and skewed variables. One-way analysis of variance (ANOVA) was used to determine differences between the means of 2 or more independent factors. Multivariate analysis was used to evaluate the possible independent factors associated with postoperative sepsis after adjusting for covariates determined by univariate analysis. Logistic regression was used to determine associations between preoperative qSOFA and SOFA scores and postoperative sepsis. The predictive accuracy of the qSOFA and SOFA scores for postoperative sepsis was evaluated using the area under the curve (AUC) of the receiver operating characteristic (ROC) curve. Cutoff values for the SOFA and qSOFA scores were defined according to Youden’s index of ROC curves for postoperative sepsis. A P-value < .05 was considered to indicate a statistically significant difference. All statistical analyses were performed using SPSS (IBM Corp. Released 2013, IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY).

3. Results

A total of 830 patients met the inclusion criteria and underwent URSL during the 72-month study period (Fig. 1), of whom 32 (3.9%) had sepsis postoperatively. The demographic data and clinical characteristics of those with and without postoperative sepsis are shown in Table 2.
The average preoperative SOFA score was 0.72 and the average preoperative qSOFA score was 0.19 (Table 2). The preoperative SOFA and qSOFA scores were significantly higher in the sepsis patients than in the non-sepsis patients (SOFA: 2.25 vs 0.66, \( P < .001 \); qSOFA: 0.88 ± 0.81 vs 0.16 ± 0.44; \( P = .003 \)) (Table 2). The surgical outcomes of URSL were shown in Table 3. In addition, the patients were more likely to get postoperative sepsis if they were older (67.38 ± 11.11 vs 55.4 ± 12.99 years; \( P < .001 \)), had DM (43.8% vs 15.8%; \( P = .009 \)), had a higher American Society of Anesthesiologists (10.0% vs 31.3%; \( P = .009 \)), had severe hydronephrosis (19.0% vs 68.8%; \( P < .001 \)), had proximal ureteral stones (41.1% vs 81.3%; \( P = .002 \)), had larger stones (12.75 ± 3.80 vs 8.26 ± 3.57; \( P < .001 \)), had a longer operative time (66.25 ± 35.58 vs 51.51 ± 25.81 minutes; \( P = .028 \)), and a longer hospital stay (7.25 ± 2.93 vs 3.74 ± 2.09 days; \( P < .001 \)) (Tables 2 and 3).

Multivariate analysis revealed that postoperative sepsis was significantly associated with older age (\( P = .04 \); OR: 1.119 (95% CI 1.036–1.209)), proximal ureteral stones (\( P = .031 \); OR: 1.138 (95% CI 1.095–2.043)), longer operative time (\( P = .028 \); OR: 1.25 (95% CI 1.035–1.671)), and severe hydronephrosis (\( P = .01 \); OR: 7.749 (95% CI 1.642–36.575)) (Table 4). The multivariate analysis also revealed that the patients who had higher preoperative qSOFA or SOFA scores were significantly more likely to have postoperative sepsis (\( P < .001 \); OR: 51.057; 95% CI: 1.035–2.043), and severe hydronephrosis (19.0% vs 68.8%; \( P = .009 \), \( P < .001 \)) (Tables 2 and 3).

We used 1-way ANOVA analysis to determine if the occurrence of comorbidities were associated with age, but these comorbidities were not risk factors for postoperative infection.

![Figure 1](image.png)

**Figure 1.** Inclusion and exclusion criteria for the ureteral stone patients in this study. Thirty-two patients were excluded because of preoperative sepsis. Besides, 58 patients with vesical or renal stones were also excluded. Total 830 patients were included to the study.
laboratory examinations, including kidney and liver function to screen whether they have potential preoperative organ failure. If the patient has a SOFA score ≥ 2, they should undergo preoperative preparation, including antibiotic treatment, nutritional support, percutaneous nephrostomy tube insertion for renal pelvis pressure decompression, minimization of the operative time, and monitoring of the pressure inside the renal pelvis during surgery to avoid excessive water pressure perfusion, etc. Taking these steps would help clinicians in the perioperative setting and during postoperative care to prevent postoperative sepsis.

In the current study, the multivariate analysis revealed that age was a significant risk factor for infection after URSL. A previous meta-analysis study also highlighted that elderly patients in some prospective studies had a higher risk of infection.[18] As the elderly are more likely to suffer from DM, cardiovascular disease and chronic obstructive pulmonary disease, sepsis often cannot be controlled once they have infection resistance.[19] Our results also showed that the patients with more proximal stones were more prone to postoperative infections, although other studies have not found an association between the location of stones and postoperative infections.[20] A possible reason for this difference is that the higher the calculus, the higher the complexity of the operation, which can lead to higher intrarenal pressure and a higher risk of sepsis. During the operation, the

### Table 2

Demographic data and clinical characteristics of the patients who received URSL.

| Characteristic                  | Non-postoperative sepsis (n = 798) | Postoperative sepsis (n = 32) | P-value |
|--------------------------------|------------------------------------|------------------------------|---------|
| Mean age ± SD                  | 55.4 ± 12.99                       | 67.38 ± 11.11                | <.001   |
| Gender                         |                                    |                              |         |
| Male                           | 540 (67.7%)                        | 26 (81.3%)                   | .411    |
| Female                         | 258 (32.3%)                        | 6 (18.8%)                    |         |
| Patient source                 |                                    |                              | .004    |
| Clinic                         | 620 (77.7%)                        | 14 (43.8%)                   |         |
| ER                             | 178 (22.3%)                        | 18 (56.3%)                   |         |
| BMI (kg/m2)                    | 26.23 ± 4.05                       | 26.34 ± 2.21                 | .002    |
| Comorbidity                    |                                    |                              |         |
| DM                             | 126 (15.8%)                        | 14 (43.8%)                   | .009    |
| HTN                            | 320 (40.1%)                        | 14 (43.8%)                   | .799    |
| Heart disease                  | 34 (4.3%)                          | 12 (38.8%)                   | .163    |
| CKD                            | 54 (6.8%)                          | 12 (37.5%)                   | .309    |
| ASA                            |                                    |                              | .009    |
| ASA I                          | 156 (19.5%)                        | 0 (0%)                       | <.001   |
| ASA II                         | 562 (70.4%)                        | 22 (68.8%)                   |         |
| ASA III & IV                   | 80 (10.0%)                         | 10 (31.3%)                   |         |
| Preoperative hydronephrosis    |                                    |                              |         |
| Moderate at most               | 646 (81.0%)                        | 10 (31.3%)                   |         |
| Severe                         | 152 (19.0%)                        | 22 (68.8%)                   | .213    |
| Preoperative ESWL*             | 76 (9.8%)                          | 6 (18.8%)                    |         |
| Preoperative antibiotics**     | 234 (29.3%)                        | 16 (50.0%)                   | .095    |
| Preoperative PCN               | 110 (13.8%)                        | 6 (18.8%)                    | .478    |
| Stone side                     |                                    |                              | .494    |
| Unilateral                     | 766 (96.0%)                        | 30 (93.8%)                   |         |
| Bilateral                      | 32 (4.0%)                          | 2 (6.2%)                     |         |
| Proximal ureter                | 328 (41.1%)                        | 26 (81.3%)                   | <.001   |
| Mean stone number ± SD         | 1.14 ± 0.5                         | 1 ± 0                        | .271    |
| Mean stone size (mm) ± SD      | 8.26 ± 3.57                        | 12.75 ± 3.80                 | <.001   |
| Preoperative qSOFA score       | 0.16 ± 0.44                        | 0.88 ± 0.81                  | .003    |
| Preoperative SOFA score        | 0.66 ± 1.06                        | 2.25 ± 1.29                  | <.001   |

ASA  = American Society of Anesthesiologists classification, BMI  = body mass index, CKD  = chronic kidney disease, DM  = diabetes mellitus, ER  = emergency room, ESWL  = extracorporeal shock wave lithotripsy, HTN  = hypertension, PCN  = percutaneous nephrostomy, qSOFA score = = (quick) sequential organ failure assessment score, SD  = standard deviation, URSL  = ureteroscopic lithotripsy.

* Preoperative ESWL was defined as patients who received ESWL within 30 d preoperatively.
** Preoperative antibiotics were used if urine analysis or culture showed bacteriuria.

### Table 3

Surgical outcomes of URSL.

| Characteristic                  | Non-postoperative sepsis (n = 798) | Postoperative sepsis (n = 32) | P-value |
|--------------------------------|------------------------------------|------------------------------|---------|
| Mean operative time (min) ± SD| 51.51 ± 25.81                      | 66.25 ± 35.58                | .028    |
| Ureteral D-J stenting          | 718 (90%)                          | 26 (81.3%)                   | .224    |
| Mean stenting days ± SD        | 12.32 ± 12.70                      | 11.31 ± 13.88                | .576    |
| Type of anesthesia             |                                    |                              | .154    |
| GA                             | 124 (15.5%)                        | 10 (31.3%)                   |         |
| SA                             | 674 (84.5%)                        | 22 (68.7%)                   |         |
| Postoperative SOFA score       | 0.44 ± 0.89                        | 4.69 ± 4.29                  | <.001   |
| Days of hospital stay ± SD     | 3.74 ± 2.09                        | 7.25 ± 2.93                  | <.001   |
| Stone free*                    | 758 (95.0%)                        | 28 (87.5%)                   | .205    |

D-J  = Double-J ureteral stenting, GA  = general anesthesia, SA  = spinal anesthesia, SD  = standard deviation, SOFA score  = sequential organ failure assessment score, URSL  = ureteroscopic lithotripsy.

* Stone free was defined as when there were no residual stone fragments larger than 3 mm.
renal pelvis must be continuously rinsed to provide the surgeon with an appropriate field of vision.

Southern et al. and Moses et al. reported that excessive operation time was associated with infection after URS.\(^{21,22}\) A longer operation time in our study was associated with postoperative sepsis, and the average operation time in our study was about 66 minutes. The length of the operation may indicate the complexity of the stone location, the patient’s anatomy, or the high pressure caused by the amount of fluid installation from the URS in the renal pelvis during ureteroscopy.\(^{23}\)

Diabetes is an important risk factor, and diabetic patients are generally believed to have a higher frequency of urinary tract infections,\(^{24}\) possibly due to an impaired immune system and white blood cell function.\(^{25}\) Although our study did not indicate that DM was a significant predictor in the multivariate analysis, it is still important to carefully consider a patient’s history of DM.

The severity of hydronephrosis was significantly associated with postoperative infection in the present study. When hydronephrosis accumulates to a severe degree, the high pressure in the renal pelvis may allow bacteria and endotoxins in the urine to be absorbed into the bloodstream, causing postoperative fever, bacteremia, and even sepsis.\(^{26}\) However, a limitation of the current study was that we did not evaluate the pressure in the renal pelvis.

We also analyzed the complications. In all 830 patients, only 2 (0.2%) had Clavien-Dindo grade IV complications. Both cases were due to septic shock after URS, and they had to be treated in the ICU (for 3 days and 5 days, respectively). Four (0.4%) patients had grade III complications, all due to ureteral perforations or stricture secondary to URS and all required re-insertion of the ureteral stenting within 1 month after URS. De la Rosette et al. analyzed 11,885 patients who received URS, and their results of infection rate, complication rate, and even stone-free rate are similar to ours\(^{2}\).

There were some other limitations to this study. First, it was a retrospective study at a single institution and only about 10% of the patients had their bilirubin level checked preoperatively. A longer operation time in our study was associated with postoperative sepsis, and the average operation time in our study was about 66 minutes. The length of the operation may indicate the complexity of the stone location, the patient’s anatomy, or the high pressure caused by the amount of fluid installation from the URS in the renal pelvis during ureteroscopy.\(^{23}\)

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### Table 4

| Factor                                | P-value | OR (95% CI)    |
|---------------------------------------|---------|----------------|
| Age                                   | .004    | 1.119 (1.036–1.209) |
| Stone site (proximal ureter or not)   | .031    | 1.138 (1.095–2.043) |
| Operative time                        | .028    | 1.25 (1.035–1.671) |
| Hydronephrosis (severe or not)        | .01     | 7.749 (1.642–36.575) |
| * High preoperative qSOFA or SOFA score | <.001  | 51.057 (2.381–42.267) |

* High score means qSOFA ≥ 1 or SOFA ≥ 2 points preoperatively.

OR = odds ratio, qSOFA score = (quick) sequential organ failure assessment score.

### Table 5

| qSOFA | Non-postoperative sepsis (n = 798) | Postoperative sepsis (n = 32) | P-value | Odds ratio |
|-------|-----------------------------------|-------------------------------|---------|------------|
| qSOFA = 0 | 698 (87.5%) | 6 (18.8%) | <.001 | 21.046 |
| qSOFA ≥ 1 | 100 (12.5%) | 26 (81.3%) |         | (4.615–95.987) |
| SOFA | <.001 | 38.798 |
| SOFA ≥ 2 | 766 (96.0%) | 6 (18.8%) |         | (8.204–183.476) |

* High qSOFA score means qSOFA ≥ 1 point, high SOFA score means SOFA ≥ 2 points.

qSOFA = quick sequential organ failure assessment, SOFA = sequential organ failure assessment.

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**Figure 2.** Receiver operating characteristic curves for qSOFA and SOFA to predict sepsis before URS. Older age, longer operative time, severe hydronephrosis, high preoperative SOFA and qSOFA score, and proximal ureteral stone were significant factors associated postoperative sepsis in multivariate analysis. Besides, the ROC of preoperative SOFA is 0.823, and 0.754 for preoperative qSOFA, which the most significant factors among them. qSOFA = quick sequential organ failure assessment, SOFA = sequential organ failure assessment, URS = ureteroscopic lithotripsy.
The bilirubin level of the patients who were not checked preoperatively was scored zero. Sepsis represents
Second, all operations were performed by residents and attending doctors with various degrees of experience. Third, we defined preoperative sepsis using the SIRS criteria because the SOFA score states that patients with sepsis must have an acute change ≥ 2 points following a dynamic review. We could only define sepsis using the SIRS criteria at a single point. Finally, our results cannot be applied to patients receiving retrograde intrarenal surgery, percutaneous nephrolithotomy, or ureterolithotomy.

5. Conclusions
The current study demonstrated that preoperative qSOFA and SOFA scores are convenient and effective tools for predicting post-URSL sepsis. Further preventive strategies should be performed in these high-risk patients. However, our results still need further external validation.

Author contributions
PJH and CYL designed the whole work and wrote the manuscript. PEH and YDW helped in analyzing the clinical data and modified the manuscript. CML, CTH, and CHL provided the statistical methods. CPH supervised and conducted the whole discussion and final interpretations.

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