



The diagnostic accuracy of urinary neutrophil gelatinase-associated lipocalin in assessing kidney function in severe hydronephrosis

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Background: Up to now, there is no perfect indicator to evaluate the renal function of severe hydronephrosis, which poses difficulties in the selection of clinical treatment decisions. This study investigates the role of neutrophil gelatinase-associated lipocalin (NGAL) in urine drained from the nephrostomy tube shortly after nephrostomy to evaluate the renal function of patients with severe hydronephrosis caused by ureteral obstruction.

Methods: The clinical data, and blood and urine samples of 24 patients with severe hydronephrosis due to ureteral obstruction were retrospectively collected. The NGAL in the urine drained from the nephrostomy tube on the morning of the first day after the procedure was measured. The glomerular filtration rate (GFR) was determined using a nuclear scan, and the clearance rate of creatinine was calculated based on nephrostomy drainage. The correlation between the NGAL level, urine volume post-nephrostomy, affected side GFR, and creatinine clearance rate (Ccr) was assessed. Moreover, the relationship between the urinary NGAL levels and prognosis was analyzed based on whether the patients underwent nephrectomy.

Results: There was a significant correlation between the urine NGAL from the nephrostomy of the affected side and the Ccr and urine volume post-nephrostomy (both $P < 0.05$). Compared with the patients in the kidney preservation group, those who underwent nephrectomy had significantly increased NGAL levels, and significantly reduced Ccrs and nephrostomy drainage urine output. Through the receiver operating characteristic (ROC) curve evaluation, the efficacy of NGAL in predicting nephrectomy was found to be superior to both the Ccr and urine output, with an area under the curve (AUC) of 0.845.

Conclusions: The NGAL in the urine shortly after nephrostomy may indicate severe renal functional deterioration.

Keywords: Hydronephrosis; neutrophil gelatinase-associated lipocalin (NGAL); glomerular filtration rate (GFR); creatinine clearance rate (Ccr); renal function

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Introduction

Background

Hydronephrosis usually results from ureteral obstruction (1). Severe hydronephrosis refers to the dilation of the renal pelvis and calyces, accompanied by the thinning of the renal cortex (2). The treatment of severe hydronephrosis needs to be determined based on the condition of the residual renal function. If the residual renal function is valuable, drainage should be improved to protect kidney function; if the residual renal function is poor, a nephrectomy should be performed directly (1). Traditionally, the glomerular filtration rate (GFR) has been used to assess unilateral kidney function. Generally, a GFR <10 mL/min/1.73 m² is considered the standard for renal dysfunction, indicating the need for nephrectomy (3). However, recent studies have shown that the GFR is not perfect in evaluating individual kidney function, and it cannot sensitively reflect changes in renal function (4,5). During our clinical practice, we have observed that some patients have a GFR >10 mL/min/1.73 m²; however, their creatinine clearance rate (Ccr) and nephrostomy urine volume remain low, and these indicators do not improve even after the obstruction has been relieved for 3 months. Therefore, a new indicator is needed to assess kidney function in severe hydronephrosis.

Neutrophil gelatinase-associated lipocalin (NGAL) is a marker of renal tubular injury (6). Urinary NGAL significantly increases after damage to the kidneys (7,8). Recent studies have shown that NGAL sensitively reflects

renal dysfunction caused by obstruction (9,10). However, there are certain limitations in the current research. For example, the specimens collected in these studies comprised urine from the bladder rather than urine from the affected kidney. To date, no study has used urinary NGAL to evaluate the function of individual kidneys.

Aim and objectives

This study sought to determine the diagnostic value of NGAL. Shortly after nephrostomy, urine was collected from the nephrostomy tube for NGAL testing. The correlations between NGAL and patients' GFR, Ccr, urine volume post-puncture, and other indicators were analyzed. The difference in the NGAL levels between the nephrectomy patients and non-nephrectomy patients were compared. Additionally, the effectiveness of NGAL in predicting the final prognosis of the kidney with severe hydronephrosis was assessed. We present this article in accordance with the STARD reporting checklist (11) (available at <https://tau.amegroups.com/article/view/10.21037/tau-24-336/rc>).

Methods

Study design

This diagnostic accuracy study examined renal function in severe hydronephrosis by prospective data collection to explore the diagnostic capabilities of NGAL.

Participants

Between July 2021 and May 2023, consecutive patients with severe hydronephrosis at the First Affiliated Hospital of Soochow University were assessed to determine their initial eligibility for inclusion in the study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics board of the First Affiliated Hospital of Soochow University (No. 2023-442) and informed consent was taken from all the patients.

To be eligible for inclusion in this study, the patients had to meet the following inclusion criteria: (I) have severe hydronephrosis (dilation of renal pelvis and thinning of renal parenchyma) diagnosed by ultrasound or computed tomography (CT) (12); (II) have hydronephrosis with a clear cause (e.g., ureteral obstruction following ureter-related surgery or tumor compression); and (III) have undergone

Highlight box

Key findings

- In our study, we find that the neutrophil gelatinase-associated lipocalin (NGAL) in the urine shortly after nephrostomy may indicate severe renal functional deterioration.

What is known and what is new?

- Up to now, the indication for the resection of severe hydronephrosis is still unclear. Glomerular filtration rate (GFR) has always been used to evaluate unilateral renal function, however, recent studies have shown that the GFR is not perfect in evaluating individual kidney function. And in our clinical work, the results of GFR are not consistent with renal function.
- This study validated the role of urine NGAL in evaluating renal function in hydronephrosis.

What is the implication, and what should change now?

- NGAL is expected to become a novel measure for assessing the renal function of patients with hydronephrosis.

anterograde imaging indicating complete ureteral obstruction (the lower end of the ureteral obstruction is completely non-opaque). Patients were excluded from the study if they met any of the following exclusion criteria: (I) had an uncontrolled severe urinary system infection; (II) had a history of chronic nephritis; (III) had blood coagulation abnormalities; (IV) had severe cardiopulmonary dysfunction and were unable to tolerate surgery; (V) had an active infectious disease; (VI) had a renal abscess; (VII) had significant hematuria after nephrostomy; and/or (VIII) had an incomplete obstruction.

Percutaneous nephrostomy and specimen collection

Percutaneous nephrostomy was performed in the Ultrasound Department by an experienced doctor. Before the procedure, the patient underwent routine blood tests and coagulation tests to rule out contraindications for nephrostomy. The patient was positioned on the healthy side, and an ultrasound examination was conducted to determine the optimal puncture site. Following disinfection, draping, and local anesthesia, a skin incision of about 0.5 cm was made. A Bard F8 one-step renal puncture nephrostomy needle was used to puncture the collecting system. The core of the needle was then removed, and the tube was sutured and secured to the skin.

The urine volume from the nephrostomy was collected from the first morning post-nephrostomy to exclude urine preserved in the hydronephrotic kidneys. NGAL in the urine from the nephrostomy was tested the first morning post-nephrostomy, typically 12–16 hours after the nephrostomy. NGAL was measured using an NGAL kit (Getein Biotech, China) with a detection range of 50–5,000 ng/mL. If the value of the sample was >5,000 ng/mL, the sample was diluted two times. If the value was <50 ng/mL, it was marked 50 ng/mL. The NGAL measurements were performed using a dry immunofluorescence method. Creatine was tested with enzymatic creatine-2 reagents (Siemens Healthcare Diagnostics Inc., 70 Watts Avenue Charlottetown, Canada); the test was based on an enzyme method. Urine was collected at 24 hours to measure the urinary creatinine levels. The patient's serum creatinine was concurrently measured to calculate the Ccr.

Radiological examination

Antegrade pyelography

Three days after the renal puncture nephrostomy, antegrade

pyelography was performed. The contrast agent used was iohexol, diluted with 0.9% saline at a saline to contrast agent ratio of 4:1. First, a kidney-ureter-bladder radiograph was taken. Next, 25–50 mL of the contrast agent was injected through the nephrostomy tube, after which the nephrostomy was clamped. The amount of contrast injected was gauged by the patient's slight discomfort on the affected side. Another radiograph was then taken, after which the patient was instructed to walk around for 10–15 minutes. An additional image was then taken. If no contrast was observed in the distal narrowed segment and the bladder, a diagnosis of complete ureteral obstruction was made.

GFR testing

The GFR test was conducted in the Outpatient Department after severe hydronephrosis was diagnosed. The Siemens E.cam SPECT instrument (Siemens, Germany) with a low-energy high-resolution collimator was used. The patient was advised to drink 400 mL of water 30 minutes before the test, and their height and weight were measured. The radioactivity count of the tracer in the syringe was also recorded. The patient then lay supine, and the probe was positioned over the lumbar region, capturing both kidneys and the bladder in the field of view. The tracer used was ^{99}Tcm -DTPA 111–185 MBq, which was given as a bolus injection via the elbow vein, followed by immediate dynamic acquisition. After the imaging was completed, the residual count in the syringe was measured under similar conditions. Using regions of interest, the outlines of both kidneys and the background were delineated. The computer processed the data based on the Gates formula, measuring the separate kidney GFR.

Indications for nephrectomy

Currently, no literature or guidelines clearly indicate the standard for nephrectomy in hydronephrosis. The standard proposed in Campbell Urology as an indicator for nephrectomy is based on the GFR (13), which is inconsistent with our clinical experience. In this study, the criteria for nephrectomy were as follows: (I) after renal puncture drainage, the average drainage from the renal fistula was <200 mL/day for 14 days with no increasing trend; and (II) a thin renal cortex as indicated by radiological CT/ultrasound. In this study, the GFR was only used as a reference for assessing renal function and not as a criterion for nephrectomy. The removed kidney was confirmed to be non-functional by pathology.

Table 1 Patient characteristics

Characteristics	Values
Age (years)	50±15
Sex	
Male	10 [41]
Female	14 [59]
BMI (kg/m ²)	22±3.0
Primary disease	
Urolithiasis	13 [55]
Stenosis from other causes	11 [45]
Laterality	
Left	8 [33]
Right	16 [67]

Values are expressed in n [%] or mean ± SD. BMI, body mass index; SD, standard deviation.

Statistical methods

The data visualization and statistical analysis were conducted using Graphpad Prism (9.0). The normally distributed continuous data are reported as the mean ± standard deviation. For the non-normally distributed data, a log transformation was applied, followed by a *t*-test for comparison. A Spearman correlation analysis was used to assess the correlation between two variables. Additionally, the receiver operating characteristic (ROC) curve and the area under the curve (AUC) were used to evaluate the value of urine NGAL, Ccr, and urine volume post-fistula creation in predicting the need for nephrectomy in patients with hydronephrosis. A *P* value <0.05 was considered statistically significant.

Results

Descriptive analysis of study data

Between July 2021 and May 2023, 30 consecutive patients with severe hydronephrosis were assessed to determine their initial eligibility for inclusion in the study. Three patients had hydronephrosis combined with infection, and three patients had incomplete obstruction indicated by antegrade angiography. Ultimately, 24 of the 30 patients were included in the study. The 24 patients had a mean age of 50 years, and mean body mass index of 22 kg/m², and 10 were male and 14 were female. Of the 24 patients, 13 had

hydronephrosis due to narrowing post-lithotripsy, 8 had had hydronephrosis due to compression from gastrointestinal tumors, and 3 had hydronephrosis due to compression from gynecological tumors. Hydronephrosis was observed in 8 patients on the left side and 16 on the right side (Table 1). All the patients underwent nephrostomy without any severe complications. Six patients experienced mild gross hematuria, which improved after the oral administration of hemostatic drugs. Figure 1 shows the study flow chart for patients, along with the final prognosis of the patients.

Correlation between NGAL and urine volume from the nephrostomy tube

The correlation between the urine NGAL obtained post-puncture and the volume of urine obtained from the renal fistula during the first 3 days post-surgery was examined, and higher urine NGAL levels were found to be significantly negatively correlated with lower urine volumes from the renal fistula, particularly on the second and third post-operative days (*P*<0.001) (Figure 2A-2C).

Correlation analysis between NGAL, the GFR, and the Ccr

We compared the immediate post-puncture urine NGAL with the patients' GFR and Ccr on the third day post-drainage on the side of the renal fistula. We found that urine NGAL was negatively correlated with the GFR on the affected side (*R*=−0.241), but this was not statistically significant. However, urine NGAL was significantly negatively correlated with the Ccr (*R*=−0.742, *P*<0.001) (Figure 2D,2E).

Comparison of NGAL, the Ccr, urine volume, and GFR on the affected side between patients in the nephrectomy and non-nephrectomy groups

In our study, seven patients ultimately underwent nephrectomy surgery. As NGAL, the post-operative urine volume, the Ccr, and the GFR did not follow a normal distribution, we applied a logarithmic transformation. These parameters were compared between the nephrectomy and non-nephrectomy groups. It was found that the urine NGAL of the nephrectomy group was significantly higher than that of the non-nephrectomy group (*P*<0.001) (Figure 3A). The Ccr of the nephrectomy group was lower than that of the non-nephrectomy group (*P*=0.01)

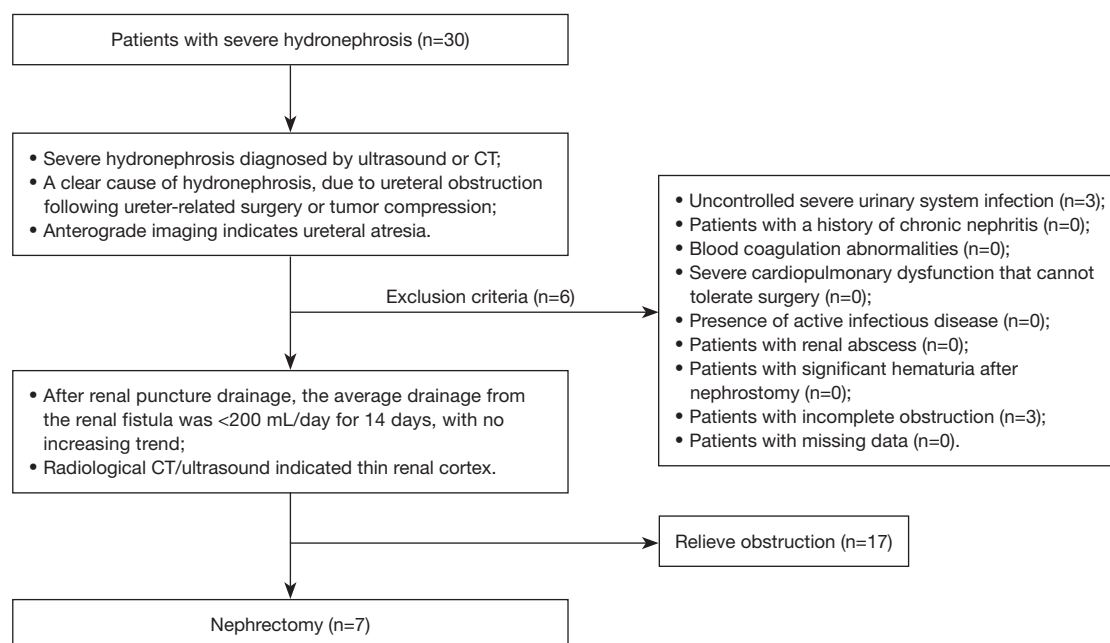


Figure 1 Study flow chart for patients. CT, computed tomography.

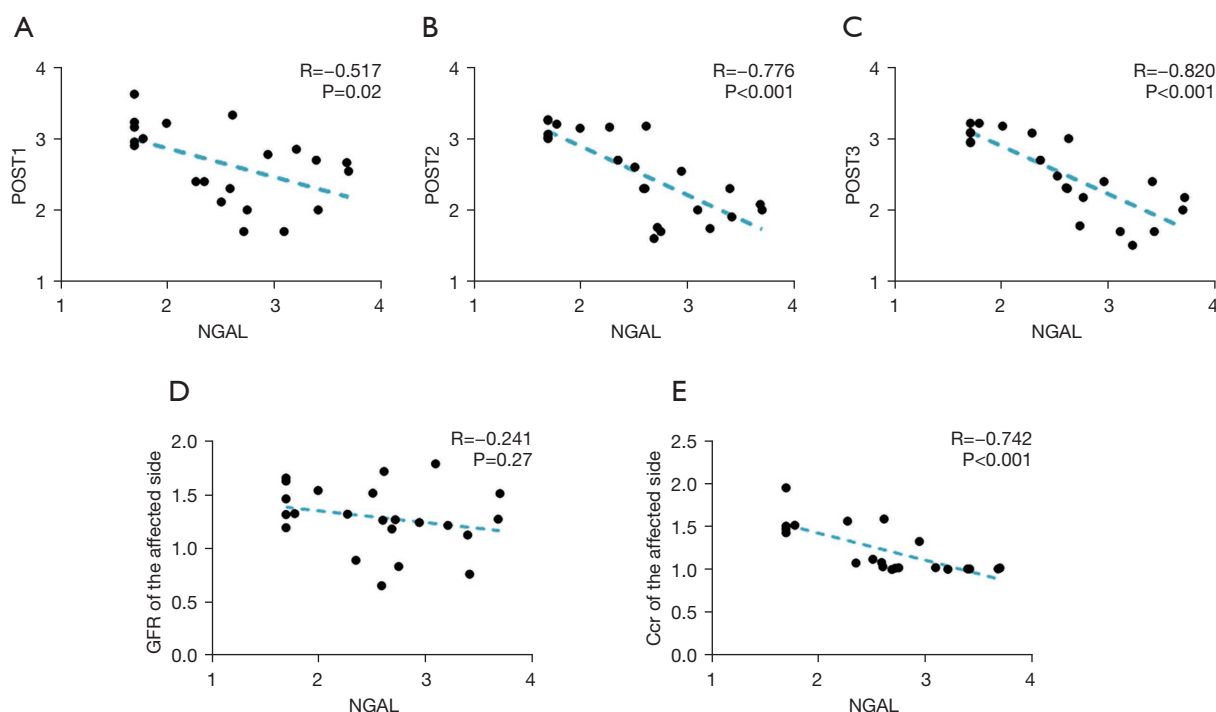


Figure 2 Correlation between NGAL and patients' clinical data. (A) Correlation between NGAL and POST1; (B) correlation between NGAL and POST2; (C) correlation between NGAL and POST3; (D) correlation between NGAL and GFR of the affected side; (E) correlation between NGAL and Ccr of the affected side. "POST1" represents the urine volume during the first day after nephrectomy from the nephrostomy tube; "POST2" represents the urine volume during the second day after nephrectomy from the nephrostomy tube; "POST3" represents the urine volume during the third day after nephrectomy from the nephrostomy tube. NGAL, neutrophil gelatinase-associated lipocalin; GFR, glomerular filtration rate; Ccr, creatinine clearance rate.

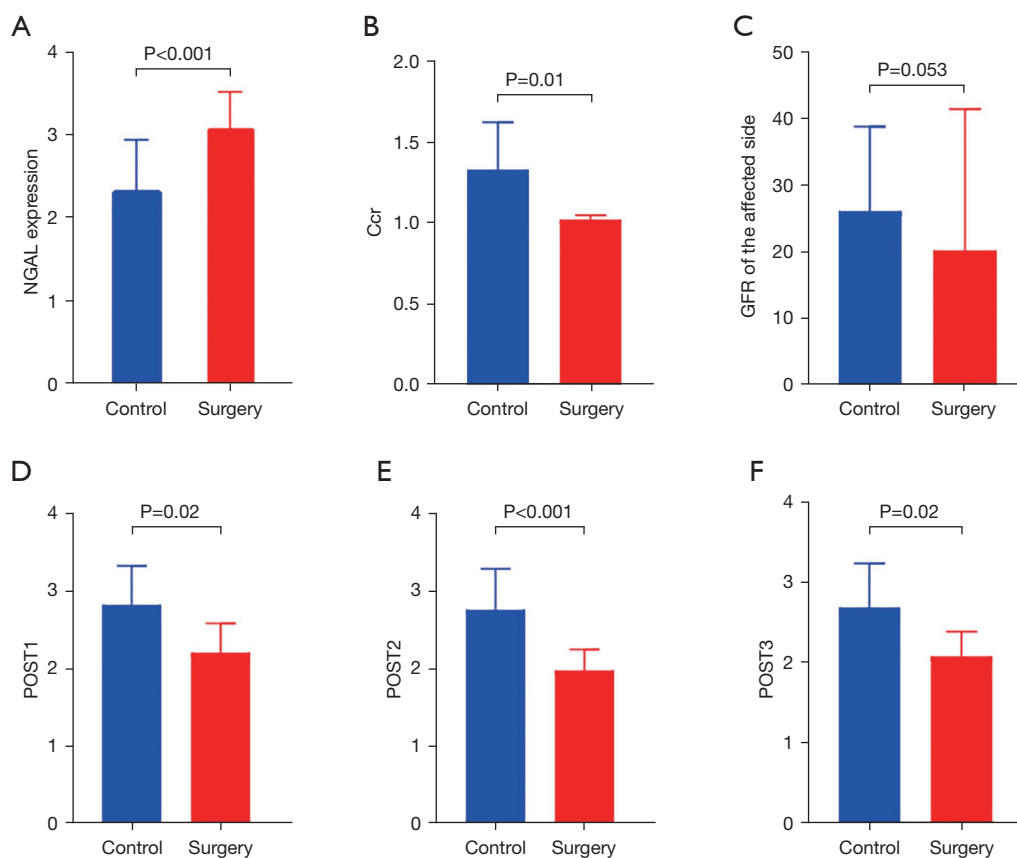


Figure 3 Comparison of the clinical data (NGAL level, the Ccr, the GFR of the affected side, and the first three urine volumes) between patients in the nephrectomy and non-nephrectomy groups. The control group refers to the non-nephrectomy group. The surgery group refers to the nephrectomy group. (A) Comparison of the NGAL level between patients in the nephrectomy and non-nephrectomy groups; (B) comparison of the Ccr between patients in the nephrectomy and non-nephrectomy groups; (C) comparison of the GFR of the affected side between patients in the nephrectomy and non-nephrectomy groups; (D) comparison of the POST1 between patients in the nephrectomy and non-nephrectomy groups; (E) comparison of the POST2 between patients in the nephrectomy and non-nephrectomy groups; (F) comparison of the POST3 between patients in the nephrectomy and non-nephrectomy groups. “POST1” represents the urine volume during the first day after nephrectomy from the nephrostomy tube; “POST2” represents the urine volume during the second day after nephrectomy from the nephrostomy tube; and “POST3” represents the urine volume during the third day after nephrectomy from the nephrostomy tube. NGAL, neutrophil gelatinase-associated lipocalin; Ccr, creatinine clearance rate; GFR, glomerular filtration rate.

(Figure 3B). The GFR of the nephrectomy group was lower than that of the non-nephrectomy group (Figure 3C), but the difference was not statistically significant. In addition, we compared the urine volumes during the first three post-operative days between the two groups. The urine volumes on the first, second, and third post-operative days in the non-nephrectomy group were all greater than those in the nephrectomy group, and the differences were statistically significant (Figure 3D–3F).

ROC analysis of the ability of NGAL, the urine volume, and the Ccr to predict nephrectomy

Due to the non-normal distribution of NGAL, the post-operative urine volume, and the Ccr, we applied a logarithmic transformation. These variables were included in the ROC curve model to predict the nephrectomy outcomes. The AUCs of these three variables were 0.845 [95% confidence interval (CI): 0.667–1, $P < 0.001$, Figure 4A, Table 2], 0.804 (95% CI: 0.608–0.999, $P < 0.001$,

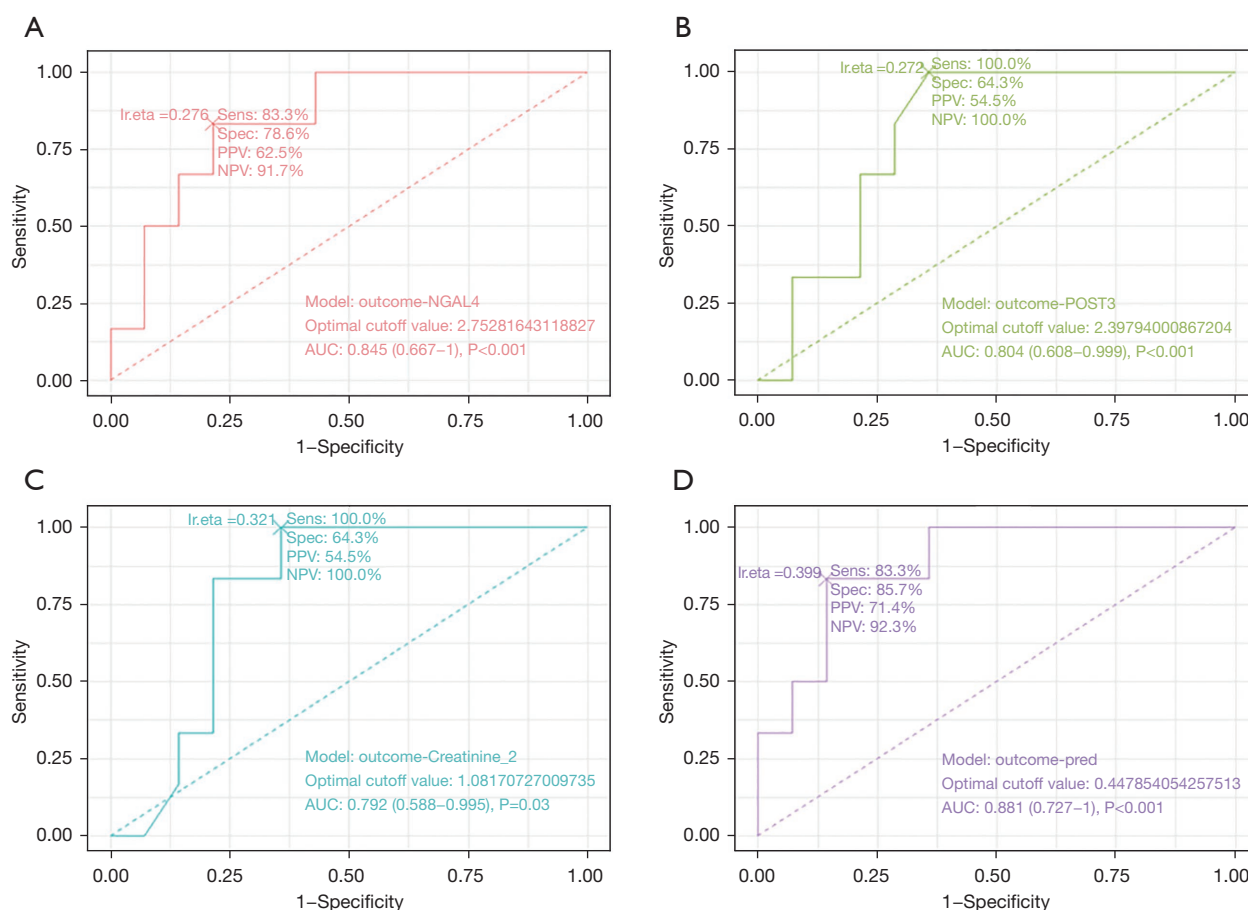


Figure 4 ROC curves showing the ability of NGAL, the urine volume, and the Ccr to predict nephrectomy in patients with severe hydronephrosis. (A) ROC curves showing the ability of NGAL to predict nephrectomy in patients with severe hydronephrosis. (B) ROC curves showing the ability of urine volume from the nephrostomy tube on the third day post-nephrectomy to predict nephrectomy in patients with severe hydronephrosis. (C) ROC curves showing the ability of the Ccr to predict nephrectomy in patients with severe hydronephrosis. (D) Combination prediction model of NGAL, the urine volume, and the Ccr. Sens, sensitivity; Spec, specificity; PPV, positive predictive value; NPV, negative predictive value; AUC, area under the curve; ROC, receiver operating characteristic; NGAL, neutrophil gelatinase-associated lipocalin; Ccr, creatinine clearance rate.

Table 2 ROC analysis results, including the AUC, cut-off, sensitivity, specificity, and P values

Index	Cut-off value	Sensitivity (%)	Specificity (%)	P value	AUC
NGAL	2.752	83.3	78.6	<0.001	0.845
Urine volume	2.397	100	64.3	<0.001	0.804
Ccr	1.081	100	64.3	0.03	0.792

ROC, receiver operating characteristic; AUC, area under the curve; NGAL, neutrophil gelatinase-associated lipocalin; Ccr, creatinine clearance rate.

Figure 4B, Table 2), and 0.792 (95% CI: 0.588–0.995, $P=0.03$, Figure 4C, Table 2), respectively, indicating that all three variables could predict the renal outcomes of patients with hydronephrosis well.

When all three variables were incorporated simultaneously into the ROC curve analysis to establish a combined prediction model of nephrectomy outcomes in hydronephrosis patients, the AUC was 0.881 (95% CI: 0.727–1, $P<0.001$, Figure 4D).

Discussion

Currently, there are numerous methods to assess residual renal function in hydronephrosis (14,15), including the GFR, renal cortex thickness measurement, and Ccr. However, each of these methods has its limitations. The GFR is the method commonly most used to assess individual renal function, and it decreases with the severity of hydronephrosis (16). However, patients may exhibit structural changes in the kidney, such as tubular damage, while their GFR remains within the normal range. In such situations, the GFR may not accurately reflect the functional status of the kidney (5). For example, in a study on chronic kidney disease, 11.1% of the patients had already exhibited structural changes, but no decline in the GFR was observed (5). In our clinical practice, we have observed similar issues. Some patients are diagnosed with severe hydronephrosis according to the radiological examination, and the drainage from the nephrostomy tube is consistently low with no increasing trend; however, their GFR is $>10 \text{ mL/min/1.73 m}^2$, which poses challenges to clinical treatment decisions.

Renal cortex thickness is commonly measured using ultrasound and CT scans. Some studies have assessed the residual renal function in hydronephrotic kidneys by measuring either the renal cortex or the renal parenchymal thickness (17,18). However, based on our clinical experience, the parenchymal thickness of a hydronephrotic kidney is heterogeneous. This may lead to greater subjectivity in the measurement.

The Ccr is an objective and efficient method for assessing renal function (19), especially for patients with unilateral complete ureteral obstruction leading to hydronephrosis. By performing a nephrostomy, the 24-hour urine output from the affected kidney can be collected. By measuring the creatinine levels in both the urine and blood, an objective measurement of the Ccr from the affected kidney can be obtained.

Some studies have suggested that for patients with poor

renal function due to obstructive causes, a percutaneous nephrostomy should be performed, and the nephrostomy tube should be left in place for 4–6 weeks to assess the recovery of renal function (20,21). However, the prolonged placement of a nephrostomy tube greatly inconveniences patients. Moreover, most patients reported in the literature are children, and, unlike in adults, complete obstruction is relatively rare in children. Pode *et al.* (22) recommended the nephrostomy be retained for 3 months to fully assess renal function, but among the 4 patients they described, those with an early low nephrostomy drainage volume eventually underwent nephrectomy. In our initial study, the nephrostomy tube was retained in patients with low nephrostomy drainage for an extended period. These patients showed no significant increase in urine output even after retaining the nephrostomy tube for 4 weeks. Thus, controversy remains as to whether it is necessary to retain the nephrostomy tube for 2–3 months to evaluate renal function.

There is currently a lack of unified guidelines on the treatment of severe hydronephrosis and whether to preserve or remove the kidney.

Partin *et al.* described the criterion as follows: “Renography can provide quantitative measures of renal function, and, in general, kidneys with less than 15% to 20% differential function are considered non-salvageable in adults” (13). This standard is based on the GFR, and the description of this standard is not clear. Thus, we propose the following standard based on the urine volume from the nephrostomy and an imaging examination: post-nephrostomy drainage for 14 days, nephrostomy drainage $<200 \text{ mL/day}$ with no increasing trend; and radiological CT/ultrasound results indicating a thin renal cortex. Pathological examinations of the removed kidneys revealed renal parenchymal atrophy and glomerular sclerosis with fibrous proliferation, indicating that the kidneys removed using these criteria were indeed non-functional. However, this method has its disadvantages. Notably, the nephrostomy needs to be retained for 2 weeks, during which time, the patient’s quality of life is adversely affected.

NGAL is a protein secreted by neutrophils found in both urine and blood, and is considered one of the biomarkers of acute kidney injury (23,24). Recently a study has evaluated its role in obstructive kidney diseases, and whether it can be used to differentiate between obstructive and non-obstructive hydronephrosis (9). Brewin *et al.* (10) conducted a systematic review of NGAL in diagnosing and prognosticating obstructive kidney diseases and found

that NGAL reflects the state of kidney hydronephrosis more sensitively than creatinine and decreases rapidly after obstruction is relieved. These studies have described the role of NGAL in obstructive kidney diseases. However, they also have their shortcomings. Notably, they all measured NGAL in the blood and bladder urine, which cannot be used to specifically assess the function of the affected kidney.

Our study evaluated the renal function of hydronephrotic kidneys by measuring the NGAL in the early drainage urine post-nephrostomy. We observed that NGAL was significantly negatively correlated with the drainage urine volume post-nephrostomy. Moreover, NGAL was also significantly negatively correlated with the Ccr of the affected kidney. The NGAL levels were significantly higher in the nephrectomy group than the kidney preservation group, suggesting that NGAL can be used to accurately evaluate kidney function. Based on the ROC curve analysis, the predictive efficacy of NGAL achieved an AUC of 0.845, indicating its accuracy in predicting the prognosis of the kidney. The use of early drainage urine post-nephrostomy has several advantages. First, the use of the drainage urine from the affected kidney nephrostomy provides an accurate representation of the affected kidney, enhancing diagnostic specificity. Second, the use of the early post-nephrostomy urine eliminates the previously suggested 3-month retention of nephrostomy, enabling the early prediction of renal function.

In the initial stages of this research, the NGAL trend in the urine within a week of nephrostomy was observed. NGAL gradually increased after nephrostomy, possibly because the procedure caused damage to the kidney, which manifested as elevated NGAL. We do not address this further in this article. NGAL increases in obstructive kidney diseases; however, its rise is negatively correlated with the prognosis of the kidney. The underlying mechanisms remain unclear. Current cytological and animal model research suggests that NGAL exerts a protective effect against kidney damage (25,26). However, the elevation of NGAL may be a protective mechanism by the body against continuous kidney damage, such that higher values might indicate more severe kidney damage.

In our study, the GFR of the nephrectomy group was lower than that of the preservation group. NGAL was negatively correlated with the GFR. The difference between the two groups was not statistically significant; however, this might have been due to the smaller number of cases included in the study, resulting in unstable statistical

results that fail to detect the true relationship. Moreover, the study design, data collection methods, patient selection, etc. might have also influenced the results.

In summary, the urinary NGAL level in early drainage post-nephrostomy can serve as an indicator for evaluating the renal function of severe hydronephrosis and can predict the value of retaining the kidney. However, this study had some limitations. It was a single-center research study with a relatively small number of cases. Further, there was a lack of long-term follow-up on the patients post-operatively. In future research, more eligible cases will be included, and long-term post-operative follow-up will be conducted.

Conclusions

The NGAL in the urine shortly after nephrostomy may indicate severe renal functional deterioration.

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Footnote

Reporting Checklist: The authors have completed the STARD reporting checklist. Available at <https://tau.amegroups.com/article/view/10.21037/tau-24-336/rc>

Data Sharing Statement: Available at <https://tau.amegroups.com/article/view/10.21037/tau-24-336/dss>

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://tau.amegroups.com/article/view/10.21037/tau-24-336/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics board of the First Affiliated Hospital of Soochow University (No. 2023-442) and informed consent was taken from all the patients.

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