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Clinical-Bladder cancer

How to manage patients with suspected upper tract urothelial carcinoma in the pandemic of COVID-19?

Hsiang-Ying Lee, MS^{a,b,c,d}, Erica On-Ting Chan, MBChB^e, Ching-Chia Li, PhD^{c,d}, David Leung, MBChB^e, Wei-Ming Li, PhD^{c,d,f}, Hsin-Chih Yeh, PhD^{a,c,d}, Peter Ka-Fung Chiu, FRCSEd(Urol)^e, Hung-Lung Ke, PhD^{c,d}, Chi-Hang Yee, FRCSEd(Urol)^e, Joseph Hon-Ming Wong, FRCSEd(Urol)^e, Chi-Fai Ng, FRCSEd(Urol)^e, Jeremy Yuen-Chun Teoh, FRCSEd(Urol)^{e,**}, Wen-Jeng Wu, PhD^{c,d,*}

^a Urology Department, Kaohsiung Municipal Ta-Tung Hospital, Kaohsiung, Taiwan

^b Graduate Institute of Clinical Medicine, College of Medicine, Kaohsiung Medical University, Kaohsiung, Taiwan

^c Department of Urology, Kaohsiung Medical University Hospital, Kaohsiung, Taiwan

^d Department of Urology, School of Medicine, College of Medicine, Kaohsiung Medical University, Kaohsiung, Taiwan

^e S.H. Ho Urology Centre, Department of Surgery, The Chinese University of Hong Kong, Hong Kong, China

^f Department of Urology, Ministry of Health and Welfare Pingtung Hospital, Pingtung, Taiwan

Received 9 June 2020; received in revised form 14 January 2021; accepted 10 June 2021

Abstract

Background: The pandemic of COVID-19 has disrupted the clinical pathway for patients with suspected upper tract urothelial carcinoma (UTUC). This aims to investigate the optimal management of UTUC during the pandemic by determining 1) Whether a three-month delay of RNU leads to worsened overall survival, 2) Whether radical nephroureterectomy (RNU) can be performed without prior diagnostic ureteroscopy (URS).

Methods: Consecutive patients with RNU performed for suspected UTUC in four hospitals in Hong Kong and Taiwan were included. Patients with histologically proven UTUC and with RNU performed within one year were dichotomized into early (≤ 3 months) and delayed (> 3 months) RNU groups. Diagnostic performances of predictive models based on pre-URS factors (gross haematuria, suspicious or malignant urine cytology, and filling defect or contrast-enhancing mass on computed tomography), with or without URS, were analysed using receiver operating characteristics and area under curve (AUC). Overall survival was analysed using Kaplan-Meier method and multivariate Cox regression analysis.

Results: Between 2000 and 2019, 665 patients underwent RNU, and 491 of them had prior diagnostic URS. The early RNU group had a better overall survival ($P = 0.015$). Early RNU was associated with a better overall survival upon multivariate analysis (HR 1.55, 95% CI 1.03–2.33, $P = 0.035$). Large tumour size, multi-focal tumour, T2 or above disease, and positive nodal status were associated with a poorer overall survival. A combination of any 2 out of the 3 pre-URS factors achieved a positive predictive value of 99.5 to 100%. Presence of all 3 pre-URS factors achieved an AUC of 0.851 with URS, and AUC of 0.809 without URS.

Conclusions: A delay of RNU for over 3 months was associated with poorer overall survival and has to be avoided despite the current COVID-19. We can also consider direct RNU based on clinical factors alone. This also avoids URS hospitalization and expedites the clinical pathway of UTUC. © 2021 Published by Elsevier Inc.

Keywords: Pandemics; Nephroureterectomy; Ureteroscopy; Mortality; Neoplasms

*Corresponding author. Tel.: +8-867-312-1101; fax: +8-867-213-8405.

**Co-correspondence author. Tel.: +8-523-505-2625; fax: +8-522-637-7974.

E-mail addresses: jeremyteoh@surgery.cuhk.edu.hk (J.Y.-C. Teoh), wejewu@kmu.edu.tw (W.-J. Wu).

1. Introduction

Upper tract urothelial carcinoma (UTUC) has an estimated annual incidence of 1–2 cases per 100,000 [1], and

it accounts for 5%–10% of all urothelial carcinomas [2]. The male to female ratio is approximately 1:1, with a similar rate of occurrence in renal pelvis and ureter [3, 4]. In some regions, the incidence of UTUC can be much higher due to various environmental factors such as aristolochic acid and arsenic exposure [2, 5, 6].

UTUCs may appear as filling defects or contrast-enhancing masses on computed tomography (CT) urography. Although the diagnostic accuracy of CT urography for UTUC is very high, ureteroscopy (URS) is still regarded a key step in establishing the diagnosis of UTUC, and in contemplating subsequent radical nephroureterectomy (RNU) [7]. A patient with localized UTUC typically requires at least 2 surgeries (URS and RNU) along the clinical management pathway.

The pandemic of COVID-19 has imposed a tremendous pressure to the provision of urological care globally. Operating theatres, in particular, have been cut down or transformed to intensive care units in hospitals where the caseload of COVID-19 becomes overwhelming [8]. Prioritization of surgery becomes a necessity in this critical time period [9]. Moreover, hospitals are high-risk areas of COVID-19 infection. Since UTUC tends to occur in the elderly population [10], our patients are prone to mortality if they are infected with COVID-19.

On the other hand, delay in cancer surgery can be deleterious to patients with UTUC. It has been shown that a delay in treatment for bladder cancer may lead to worsened survival [11, 12], but data on UTUC is extremely limited. We need to understand what extent of ‘delay’ is considered acceptable before we can make a sensible decision on the optimal management of UTUC. Moreover, in the clinical pathway of UTUC, there is a possibility of proceeding directly to RNU without prior diagnostic URS. This may potentially expedite the management of UTUC while minimizing the potential exposure to COVID-19.

In this study, we tried to answer two main questions in the clinical management of UTUC, 1) Whether a three-month delay of RNU leads to a worse survival outcome, 2) Whether we can proceed directly to RNU without prior diagnostic URS. The results are expected to provide valuable insights on the optimal management of UTUC in the pandemic of COVID-19.

2. Material and methods

This is a multi-centre retrospective cohort study involving Prince of Wales Hospital, North District Hospital in Hong Kong, and Kaohsiung Medical University Hospital and Kaohsiung Municipal Ta-Tung Hospital in Taiwan. Patients with suspected primary UTUC undergoing RNU between 2000 and 2019 were included. Patients with a history of muscle invasive bladder cancer prior to UTUC were excluded. All patients were followed up primarily with CT scan in line with the recommendations from the EAU guidelines [13]. Patient and disease characteristics were

reviewed. Dates of first consultation and RNU, and URS and RNU pathology results were recorded. Overall survival (OS) was reviewed. Ethics approval was obtained for this study (Reference no.: KMUHIRB-E(I)-20180214).

The clinical diagnosis based on pre-URS factors (gross hematuria, suspicious or malignant cells on urine cytology, and filling defect or contrast-enhancing mass on CT urography), and the URS diagnosis based on endoscopy and histology results, were compared with the final RNU pathology results. Different combinations of predictive models were developed using logistic regression. The diagnostic performances were analyzed using receiver operating characteristics (ROC) and area under curve (AUC). Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were also calculated.

Only patients with histology-confirmed UTUC and RNU performed within one year were included in the survival analysis. The patients with an interval of over 1 year from the date of first consultation to RNU were excluded from the survival analysis. Patients were then dichotomized (≤ 3 months vs. > 3 months) according to the time from the date of first consultation to the date of RNU. There was very limited data on the effect of delayed RNU in the literature, so we took reference from studies on bladder cancer and decided to use 3 months as a cut-off [11, 12, 14]. Gore et al. reviewed a cohort of patients who had stage 2 transitional cell carcinoma and received radical cystectomy from 1992 to 2001, coming up with a conclusion that delay in definitive surgical treatment for over 12 weeks increases both cancer-specific and overall mortality (HR 2.01, $P = 0.003$) [11]. Another study by Lee et al. also found that cystectomy which delayed for more than 93 days resulted in increased risk of disease-specific (HR 2.12, $P = 0.08$) and overall mortality (HR 1.96, $P = 0.04$) [12]. Baseline characteristics were compared. Survival analysis was performed using Kaplan-Meier analysis and multivariate Cox regression analysis. All statistical analyses were performed using SPSS version 20.0. A P value of < 0.05 is considered statistically significant.

3. Results

From 2000 to 2019, 665 patients with suspected UTUC underwent RNU. The mean age was 67.9 ± 10.4 years, and 49% were male patients. The median follow-up was 40 months.

Among the 660 patients with histology-confirmed UTUC, 49 patients had RNU over 1 year after the first consultation and were excluded from the survival analysis. Another 11 patients were excluded from the survival analysis because of missing data on the duration between first consultation and RNU. In the remaining 600 patients, there were 432 patients in the early RNU group and 168 patients in the delayed RNU group. There were no significant differences in terms of age, gender, baseline renal function, tumor size, tumor multi-focality, pathological T-staging,

Table 1
Comparison of patient and disease characteristics between the early and delayed RNU groups

	Early RNU group (n=432)	Delayed RNU group (n=168)	P value
Age (years)	67.6 +/- 10.4	68.1 +/- 11.0	0.581
Gender (Female)	226 (52.4%)	77 (46.1%)	0.165
Baseline creatinine (umol/L)	188.2 +/- 243.3	154.4 +/- 161.4	0.103
ASA			
ASA 1	27 (7.0%)	18 (11.2%)	<0.001
ASA 2	109 (28.2%)	74 (46%)	
ASA 3 or above	250 (64.8%)	69 (42.9%)	
Tumour size (mm)	31.5 +/- 21.2	30.7 +/- 22.1	0.679
Tumour multifocality	111 (25.7%)	46 (27.4%)	0.673
Pathological T-staging			
Ta	56 (14.1%)	24 (14.9%)	0.521
T1	89 (22.4%)	29 (18%)	
T2 or above	253 (63.6%)	108 (67.1%)	
Pathological N-staging			
Nx / N0	398 (92.1%)	158 (94%)	0.418
N1 or above	34 (7.9%)	10 (6%)	
Tumour grade			
Grade 1	52 (13.5%)	25 (17.4%)	0.015
Grade 2	37 (9.6%)	25 (17.4%)	
Grade 3	297 (76.9%)	84 (65.4%)	
Carcinoma-in-situ	16 (3.7%)	4 (2.4%)	0.418
Lymphovascular invasion	102 (24.6%)	31 (19.1%)	0.163
Lymph node dissection	7 (4.8%)	11 (10.9%)	0.068
Adjuvant chemotherapy	76 (17.6%)	13 (7.7%)	0.002

ASA = American Society of Anesthesiologists.

pathological N-staging, presence of carcinoma in-situ, lymphovascular invasion and lymph node dissection. The early RNU group had a higher ASA grading ($P < 0.001$), a higher tumor grading ($P = 0.015$) and a higher rate of adjuvant chemotherapy ($P = 0.002$) than the delayed RNU group (Table 1).

The early RNU group had a better overall survival than the delayed RNU group upon Kaplan-Meier analysis ($P = 0.015$) (Fig. 1). Upon multivariate Cox regression analysis, early RNU within 3 months was associated with a better overall survival (HR 1.55, 95% CI 1.03-2.33, $P = 0.035$). Larger tumor size (HR 1.01, 95% CI 1.00–1.02, $P = 0.029$), multi-focal tumor (HR 1.62, 95% CI 1.06–2.48, $P = 0.026$), T2 or above disease (HR 3.53, 95% CI 1.17–10.66, $P = 0.026$), and positive nodal status (HR 2.79, 95% CI 1.46–5.32, $P = 0.002$) were associated with a poorer overall survival (Table 2).

All 665 patients were included in the predictive models analysis. Upon presentation, 80.1% had gross hematuria and 26% had suspicious or malignant cells on urine cytology. Regarding the CT urography results, 97% had filling defect or contrast-enhancing mass, and the rest had non-specific findings such as urothelial thickening and hydronephrosis. Overall, 74% had diagnostic URS before undergoing RNU. For those without prior diagnostic URS, 99.4% were confirmed to have UTUC in the RNU pathology (Fig. 2).

The diagnostic performances of the predictive models based on pre-URS factors, with or without URS, were shown in Table 3. Overall, the addition of URS increased the AUCs of the models based on pre-URS factors alone. Of note, the presence of all pre-URS factors, together with URS, achieved the best diagnostic performance with an AUC of 0.851. The presence of all pre-URS factors, but

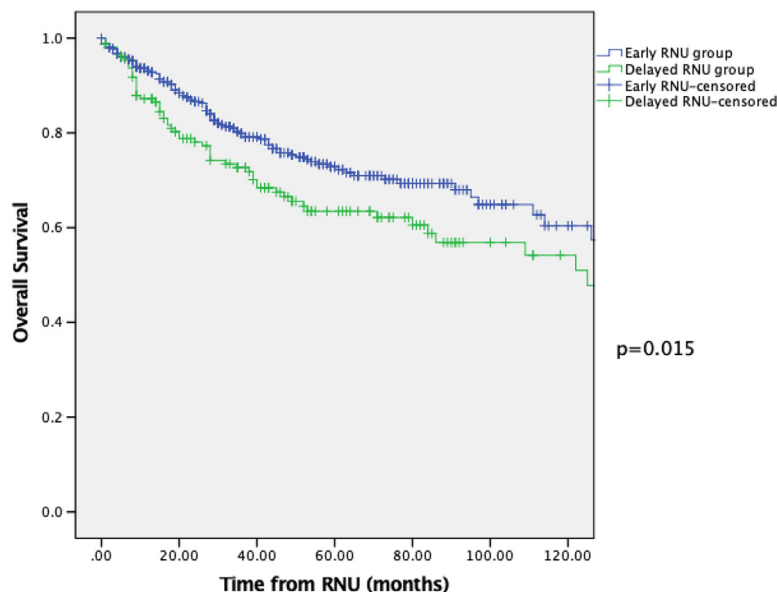


Fig. 1. Kaplan-Meier analysis of overall survival in early versus delayed RNU groups. RNU: Radical nephroureterectomy.

Table 2
Multivariate Cox regression analysis on overall survival

	HR	95% CI		P value
		Lower	Upper	
Age >70 y old	1.41	0.94	2.11	0.096
Gender	1.22	0.82	1.80	0.325
Baseline renal function	1.00	1.00	1.00	0.727
ASA				
ASA 1	1.00 (Ref)	-	-	-
ASA 2	0.74	0.38	1.43	0.369
ASA 3 or above	0.85	0.43	1.69	0.639
Tumor size	1.01	1.00	1.02	0.029
Tumor multi-focality	1.62	1.06	2.48	0.026
Pathological T staging				
Ta	1.00 (Ref)	-	-	-
T1	2.16	0.67	7.01	0.199
T2 or above	3.53	1.17	10.66	0.026
Positive nodal staging	2.79	1.46	5.32	0.002
Tumor grade				
Grade 1	1.00 (Ref)	-	-	-
Grade 2	1.25	0.51	3.06	0.622
Grade 3	1.22	0.54	2.78	0.636
Carcinoma-in-situ	0.00	0.00	0.00	0.963
Lymphovascular invasion	1.31	0.81	2.11	0.277
Adjuvant chemotherapy	1.50	0.86	2.61	0.150
RNU within 3 months	1.55	1.03	2.33	0.035

ASA = American Society of Anesthesiologists; CI = Confidence interval; HR = Hazard ratio; RNU = Radical nephroureterectomy.

without URS, also achieved an AUC of 0.809. Even without URS, the presence of any 2 out of the 3 pre-URS factors achieved an AUC of over 0.7 consistently. Regardless of the model we used, with or without URS, all of them achieved a near 100% PPV. On the other hand, NPV was very low (0.6%–3.1%) in all predictive models.

4. Discussion

COVID-19 is a global pandemic with a record of more than 91 million cases, and 1.95 million deaths as of 12th January 2021. The surge in COVID-19 cases has resulted in overloaded health care systems, leading to a potential need of diversion of health worker as well as ventilator level of care for COVID-19 patients. Hospitals are also high-risk areas for COVID-19 infection, so hospitalization for URS and RNU may impose additional infective risks to our patients. Surgical prioritization becomes a necessary compromise during this critical time period of COVID-19. Under this context, there were several published recommendations to guide our clinical practice [9, 15, 16]. These recommendations were extremely timely and valuable, but the evidence on UTUC in particular was very limited.

This multi-centre study included a large number of patients undergoing RNU for suspected UTUC in Taiwan and Hong Kong. Our study showed that a 3-month delay of RNU resulted in a poorer overall survival, and this remains as a significant risk factor after adjusting for other confounding factors. Upon literature review, there were three studies which provided data regarding the effects of delayed RNU / conservative treatment on UTUC patients. Lucas *et al.* reported a cohort comparing immediate RNU (79 patients) and delayed RNU (11 patients); the 5-year overall survival rates were 71.5% in the immediate RNU group and 45% in the conservative treatment group [17]. Gadzinski *et al.* had a similar comparative study on immediate RNU (62 patients) and delayed RNU (11 patients); the 5-year overall survival rates were similar between the 2 groups [18]. However, both studies were limited by their small sample size, and there was no specific cut-off to define the duration of delay. Lee *et al.* investigated the impact of surgical waiting time using one month as a cut-off. In a cohort

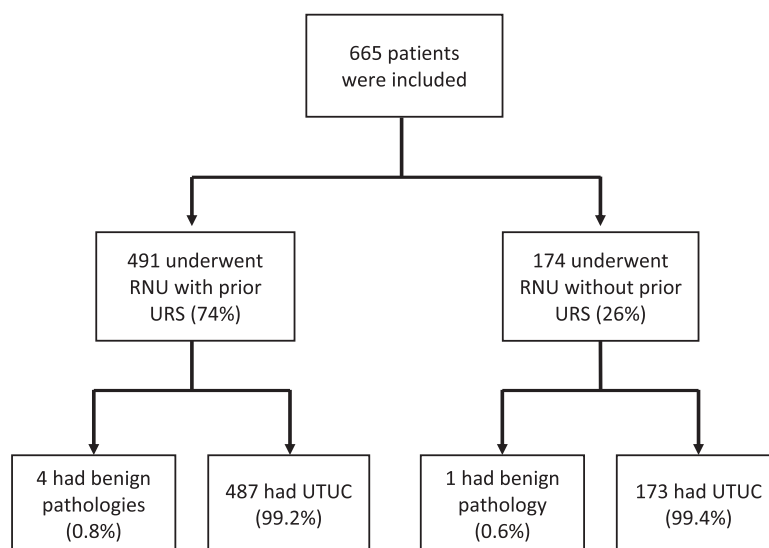


Fig. 2. Patient flow diagram for UTUC diagnosis.

Table 3
Diagnostic performances of pre-URS factors, with and without URS

Gross hematuria	Abnormal cytology (Suspicious / malignant)	Abnormal CT scan (Filling defect / contrast-enhancing mass)	Without URS				
			Sn	Sp	PPV	NPV	AUC (95% CI)
+	+		11%	100%	100%	0.6%	0.715 (0.516-.913)
+		+	82%	100%	100%	3.1%	0.736 (0.459-1.000)
	+	+	11%	100%	100%	0.6%	0.775 (0.562-0.988)
+	+	+	9.8%	100%	100%	0.6%	0.809 (0.606-1.000)
Gross hematuria	Abnormal cytology (Suspicious / malignant)	Abnormal CT scan (Filling defect / contrast-enhancing mass)	With URS				
			Sn	Sp	PPV	NPV	AUC (95% CI)
+	+		24%	100%	100%	1.1%	0.766 (0.629-.903)
+		+	76%	50%	99.5%	1.7%	0.783 (0.562-1.000)
	+	+	31%	100%	100%	1.2%	0.842 (0.695-0.989)
+	+	+	24%	100%	100%	1.1%	0.851 (0.697-1.000)

AUC = Area under curve; CT = Computed tomography; NPV = Negative predictive value; PPV = Positive predictive value; Sn = Sensitivity; Sp = Specificity; URS = Ureteroscopy.

of 138 patients [19], cancer-specific survival was similar between early and delayed RNU. However, no data on overall survival was provided. We also performed an additional exploratory analysis using <1 month, 1–3 months, and >3 months as cut-offs; when compared with the <1 month group, overall survival was significantly worse in the >3 months group (HR 2.04, 95% CI 1.17–3.57, $P = 0.012$), but not in the 1–3 months group (HR 1.49, 95% CI 0.88–2.53, $P = 0.138$).

Our results also showed that the addition of URS consistently improved AUC in all predictive models based on pre-URS factors. URS is a relatively simple surgery that may provide reassurance to both patients and urologists before a major decision towards RNU. On the other hand, we noted that the diagnostic performances of the predictive models based on pre-URS factors alone were indeed very acceptable. An AUC of 0.809 was achieved when there is presence of gross hematuria, suspicious or malignant cells on urine cytology, and filling defect / contrast-enhancing mass on CT urography. Among the pre-URS factors, the presence of filling defect / contrast-enhancing mass appeared to add the greatest diagnostic value, followed by the presence of suspicious or malignant cells on urine cytology, and the presence of gross hematuria. Regardless of which model we used, all achieved a near 100% PPV based on pre-URS factors alone. Albeit the fear of benign pathology upon RNU, this possibility is very low if any two out of the three pre-URS factors were present.

Our results have important clinical implications in the pandemic of COVID-19. First, although surgical prioritization is a problem we need to face in reality, a delay of more than 3 months does lead to deleterious effects in terms of overall survival. We must try our best to avoid delaying

RNU for more than three months despite the current COVID-19 situation. Second, the PPVs of the predictive models were extremely high as soon as 2 out of 3 pre-URS factors were present. We can potentially avoid URS hospitalization and expedite the clinical pathway by proceeding directly to RNU, provided that our patients are well informed about the reasoning behind. The implication for the potentially expedited clinical pathway is especially significant in resources-limited region where patients have to wait a significant period of time before having a URS.

To our knowledge, this is the largest study investigating the effects of delayed RNU on survival outcomes. Our study provided data using a solid primary outcome of overall survival; cancer-specific survival was not used to avoid bias from subjective judgment. On the other hand, our study is limited by its retrospective nature. There is a lack of standardized follow-up protocols, so this may lead to data inaccuracies. Another limitation is that the older 1973 WHO Classification was used for tumor grading in our analysis since our cohort of UTUC patients dated from 2000 to 2019. Since only patients who underwent RNU were included in this study, there is a potential selection bias overestimating the diagnostic performances of our predictive models. Nevertheless, this represents the best available data in the current literature and we hope these results can provide valuable insights regarding the management of UTUC in the current pandemic of COVID-19.

5. Conclusions

Delaying RNU for more than three months was associated with poor overall survival. Despite the critical situation of COVID-19, we should try our best to avoid delaying

RNU for more than 3 months. Pre-URS factors can predict the pathology of UTUC very well, and we can consider proceeding directly to RNU without prior diagnostic URS. This can potentially avoid the URS hospitalization and expedite the management of UTUC. Further studies are warranted to validate this postulation.

Supplementary materials

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urolonc.2021.06.007>.

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