Application of the Paris Reporting System for Urine Cytology: The Three-Year Experience of a Single Tertiary Care Institute in Thailand

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Keywords

Paris System · Urine cytology · Risk of high-grade malignant neoplasm · Single institute in Thailand

Abstract

Introduction: Urothelial carcinoma is one of the most common human cancers, both in Thailand and worldwide. Urine cytology is a screening tool used to detect urothelial carcinoma. The Paris System for Reporting Urinary Cytology (TPSRUC) was first published in 2016 to standardize the procedures, reporting, and management of urothelial carcinoma. Diagnostic categories include negative for high-grade urothelial carcinoma (NHGUC), atypical urothelial cells (AUCs), suspicious for HGUC (SHGUC), HGUC, low-grade urothelial neoplasm, and other malignancies. **Material and Methods:** In a retrospective review, urine cytology specimens from 2016 to 2019 were reevaluated using the TPSRUC. The risk of high-grade malignant neoplasm (ROHM) for each diagnostic category was calculated. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of prediction of high-grade malignant neoplasms were evaluated for cases with histological follow-up specimens. **Results:** In total, 2,178 urine cytology specimens were

evaluated, of which 456 cases had follow-up histological specimens. The ROHM in each diagnostic category was as follows: NHGUC, 17.4%; AUC, 49.9%; SHGUC, 81.2%; HGUC, 91.3%; and other malignant neoplasms, 87.5%. The sensitivity, specificity, PPV, NPV, and accuracy for high-grade malignant neoplasm prediction were 63%, 92.8%, 89%, 73.1%, and 78.5% when AUC was included as malignant in the comparison and 82.6%, 74.7%, 75.1%, 82.3%, and 78.5% when AUC was not considered malignant. **Conclusions:** TPSRUC provides reliable results that are reproducible by different interpreters and is a helpful tool for the detection of HGUC.

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Introduction

Urothelial carcinoma is the 10th most common cancer in the world [1] and the 15th most common in Thailand [2]. Diagnosis of urothelial carcinoma can be made in several ways including cystoscopic evaluation and biopsy, urine cytology, and urine biomarkers. Although surgical histopathological diagnosis is the gold standard for urothelial carcinoma, urine cytology is a noninvasive, easy, and cost-effective method of screen-

Table 1. Urine cytology specimens (diagnostic categories, age, gender, and specimen type)

Cytologic diagnostic category	ND	NHGUC	AUC	SHGUC	HGUC	Other neoplasms	Total
Case, <i>n</i> (%)	13 (0.6)	1,657 (76.1)	303 (13.9)	59 (2.7)	133 (6.1)	13 (0.6)	2,178
Age (average)	36–85 (61)	10–96 (65)	3–96 (66)	28–89 (69)	28–89 (69)	39–78 (61)	3–96 (66)
Gender (M:F)	10:3	902:755	203:100	38:21	85:30	10:3	1,258:920
<i>Type of specimen</i>							
Voided	7	881	165	25	48	6	1,132
Instrument	6	759	137	33	85	7	1,027
Neobladder	–	9	1	1	–	–	11
Unspecified	–	8	–	–	–	–	8

ND, nondiagnostic.

ing, monitoring, and surveillance [3–7]. While previous reporting systems for urine cytology have been developed to standardize diagnosis and clinical management, some diagnostic categories lacked specific or reproducible criteria for meaningful diagnosis. The Paris System for Reporting Urinary Cytology (TPSRUC) attempts to address these problems by focusing on morphologically detectable high-grade urothelial carcinoma (HGUC) and features that relate to HGUC. TPSRUC also constrains the historically poorly reproducible attempts at diagnosis of low-grade urothelial neoplasia. TPSRUC emerged at the 2013 International Cytology Congress in Paris, France, and was officially released in 2016 [3, 8]. The primary purpose of this system is to detect HGUC [3, 7]. The diagnostic categories of this reporting system are negative for HGUC (NHGUC), atypical urothelial cells (AUCs), suspicious for HGUC (SHGUC), HGUC, low-grade urothelial neoplasm (LGUN), and other malignancies. A secondary purpose of the TPSRUC was to replace the existing diagnostic category of “atypical urothelial cells” with a more reproducible and clinically meaningful model [9]. Our institute has been utilizing TPSRUC in urine cytology diagnoses for 3 years (2016–2019). This study offers an evaluation of this reporting system and examines the correlations between cytological and histopathologic diagnoses.

Materials and Methods

This was a retrospective cross-sectional study. All cytology urine specimens obtained between October 2016 and September 2019 were retrieved from the laboratory information system of our institute (developed by institute’s health information technology unit). For each patient specimen, the patient’s gender and age, the

specimen collection date, the type of cytology specimen (voiding and instrument), and the type of surgical pathological specimen (biopsy, transurethral resection of bladder tumor, and organ resection) were recorded. The data were gathered anonymously to protect patient confidentiality.

All urine cytology specimens were prepared as ThinPrep slides (Hologic Inc., Marlborough, MA, USA) and stained with Papanicolaou stain. The TPSRUC diagnostic categories were used to group the specimens. These are NHGUC, AUC, SHGUC, HGUC, LGUN, other malignant neoplasms, and nondiagnostic. The latter category was applied to those samples insufficient for cytological diagnosis.

For each cytology specimen, details of any subsequent specimens collected from the same patient in the subsequent year were obtained. When more than one additional surgical specimen was available, the sample with the most severe result was selected for use in this study. Correlated surgical specimens were categorized as negative for neoplasm (i.e., nonneoplastic tissue, cystitis, infection, and reactive change), HGUC (i.e., urothelial carcinoma in situ, infiltrating, and noninvasive HGUC), LGUN (i.e., papilloma, papillary urothelial neoplasm of low malignant potential, and low-grade urothelial carcinoma), and nonurothelial neoplasm. All cases of discordance between surgical pathological and cytological diagnoses were reviewed by cytopathologists and surgical pathologists separately.

The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and risk for high-grade malignant neoplasm (ROHM) were determined. The ROHM was evaluated for specimens in each diagnostic category, including the surgical category of high-grade carcinoma and other high-grade malignant neoplasms. Statistical Package for the Social Sciences for Windows (SPSS Inc.) was used for statistical analysis.

Results

Clinical Data and Specimen Types

In total, 2,178 cytology specimens collected between October 2016 and September 2019 were included in this study. The average patient age was 66 years (range = 3–96 years). The sample was composed of 1,258

Fig. 1. a Cytological features of a case NHGUC demonstrated benign intermediate urothelial cells. These cells exhibited round-oval, centrally located nuclei, smooth nuclear membrane, evenly distributed fine chromatin, and low N/C ratio (Papanicolaou stain,

×400). **b** Histology of the subsequent surgical specimen showed polypoid urothelial mucosa, edematous stroma, and chronic inflammation in lamina propria. The pathologic diagnosis in the case pictured was polypoid cystitis (H&E stain, ×100).

Table 2. Correlations between urine cytology categories (based on TPSRUC) and subsequent surgical samples

Cytologic diagnostic category	ND	NHGUC	AUC	SHGUC	HGUC	Other neoplasm	Total
Case, <i>n</i> (%)	2 (0.4)	213 (46.7)	86 (18.9)	32 (7.0)	115 (25.2)	8 (1.8)	456
Negative for neoplasm, <i>n</i> (%)	1 (50.0)	140 (65.7)	28 (32.6)	4 (12.5)	4 (3.5)	1 (12.5)	178 (39.0)
LGUN, <i>n</i> (%)	–	34 (16.0)	13 (15.1)	2 (6.3)	6 (5.2)	–	55 (12.1)
HGUC, <i>n</i> (%)	1 (50.0)	28 (13.2)	33 (38.4)	22 (68.7)	103 (89.6)	3 (37.5)	190 (41.7)
Other malignant neoplasms, <i>n</i> (%)	–	9 (4.2)	10 (11.6)	4 (12.5)	2 (1.7)	4 (50.0)	29 (6.3)
Suboptimal, <i>n</i> (%)	–	2 (0.9)	2 (2.3)	–	–	–	4 (0.9)

ND, nondiagnostic.

(58%) men and 920 (42%) women (the ratio of men to women was 1.4:1). The types of urine specimen included 1,132 (52%) from voided urine, 1,207 (47%) instrument, 11 (0.5%) neobladder, and 8 (0.4%) from unspecified sites.

Cytological Diagnoses

The diagnostic categories of our cytology specimens are shown in Table 1. Majority of the sample were negative for HGUC (1,657 cases, 76.1%). The remaining were diagnosed as follows: 303 cases (13.9%) of AUC, 59 cases of SHGUC (2.7%), 133 cases (6.1%) of HGUC, and 13 cases (0.6%) of other malignant neoplasms. Thirteen cases (0.6%) were suboptimal for evaluation due to acellular or severe paucicellular specimens. None of our samples were diagnosed with LGUN.

Histologic Diagnoses and Cytological-Histologic Correlations

As shown in Table 2, 456 cases (21% of cytology specimens) provided a subsequent histological sample after cytology diagnosis. The histology diagnoses in these cases were HGUC, negative for neoplasm, LGUN, other malignant neoplasms, and suboptimal specimens in 190 (41.7%), 178 (39%), 55 (12.1%), 29 (6.3%), and 4 (0.9%) cases, respectively. The other neoplasms included prostatic adenocarcinoma, colonic adenocarcinoma, gastric adenocarcinoma, clear cell renal cell carcinoma, collecting duct carcinoma, squamous cell carcinoma, and diffuse large B-cell lymphoma. Based on TPSRUC diagnostic categories, the cytology specimens of these 456 cases were categorized into NHGUC, AUC, SHGUC, HGUC, and other neoplasms in 213 (46.7%), 86 (18.9%), 32

Fig. 2. **a, c** Cytological features of AUCs exhibited nonsuperficial urothelial cells with an increased N/C ratio (>0.5), mild hyperchromasia, and nuclear irregularity (Papanicolaou stain, $\times 400$). **b** Histology of the surgical specimen subsequent to the cytology specimen in **a** showed polypoid thickened urothelial mucosa without cytologic atypia, edematous stroma, and chronic inflammatory cells in lamina propria. The pathological diagnosis was polypoid

cystitis with urothelial hyperplasia (H&E stain, $\times 100$). **d** Histology of the surgical resection specimen subsequent to the cytology specimen in **c** demonstrated confluent delicate papillae lined by AUCs. These cells were moderate to marked cytologic pleomorphism. The pathological diagnosis was high-grade papillary urothelial carcinoma at the ureter (H&E stain, $\times 40$).

(7.0%), 115 (25.2%), and 8 (1.8%) cases, respectively. Only 2 (0.4%) cases were deemed nondiagnostic. The instances of cytological-histological correlation are shown in Figures 1–3.

The ROHM for each category was as follows: NHGUC, 17.4%; AUC, 49.9%; SHGUC, 81.2%; HGUC, 91.3%; and other neoplasms, 87.5%. The sensitivity, specificity, and accuracy (including SHGUC, HGUC, and other malignant neoplasms) were 63%, 92.8%, and 78.5%, respectively. The PPV and NPVs were 89% and 73.1%. When the AUC category was considered as malignant cases, the sensitivity increased from 63% to 82.6%, but the specific-

ity decreased from 92.8% to 74.7%. Diagnostic accuracy was 78.5%. The PPV and NPV were 75.1% and 82.3%, respectively.

For NHGUC, 37 cases were discordant (28 cases were subsequently diagnosed as HGUC and 9 as other malignant neoplasms). Eleven cases were found to be high-grade neoplasms in the upper tract. Eight of these showed paucicellular specimens, and 6 were other malignant neoplasms involving the urinary bladder and kidneys.

In urine cytology diagnoses, 17 cases showed HGUC, which were negative or low-grade in histology diagnoses. Eight of these were LGUNs, and 9 were negative for neo-

Fig. 3. **a, c** Cytological features of cases diagnosed as SHGUC (**a**) and HGUC (**c**) showed nonsuperficial urothelial cells with a significantly increased N/C ratio (>0.7), hyperchromasia, clumped chromatin, and nuclear irregularity but fewer neoplastic cells in SHGUC (Papanicolaou stain, $\times 400$). **b, d** Histology of the surgical

specimens subsequent to the cytology specimens in **a** and **c**, respectively, showed frequently fused papillae and was lined by moderate to marked atypia of urothelial cells. The pathological diagnoses of these specimens were papillary HGUC (H&E stain, $\times 100$).

plasms. In the AUC cytological category (18.9% of cases), 33 cases were diagnosed as HGUC, 10 as other malignant neoplasms, and 2 as suboptimal specimens in subsequent histological diagnosis.

Discussion

Urine cytology is a simple tool for screening and surveillance of urothelial carcinoma. TPSRUC has become the primary system for the standardization of urine cytology diagnosis at our institute. It facilitates accurate detection and guides the clinical management of HGUC.

In this current retrospective study, we aimed to evaluate our institute's 3-year experience of TPSRUC and de-

termine the level of correlation between TPSRUC-guided urine cytology and subsequent histological diagnosis to establish the diagnostic accuracy of this system and its limitations. TPSRUC was used in the diagnosis of 2,178 urine samples, of which 456 cases had subsequent histological specimens that could be used for comparison.

After TPSRUC implementation, multiple previous studies have demonstrated an improvement in diagnostic efficiency with TPSRUC compared to the conventional reporting system [5, 7, 10]. The system's sensitivity, specificity, and accuracy in distinguishing high-grade malignant neoplasms from nonneoplastic and low-grade lesions are shown in Table 3. The sensitivity ranged from 40% to 87.1%, specificity from 78.4% to 100%, PPV from 81% to 100%, NPV from 61% to 88.2%, and accuracy

Table 3. Summary of the diagnostic parameters of TPSRUC

	Case, <i>n</i>	Sensitivity, %	Specificity, %	PPV, %	NPV, %	Accuracy, %
Danakas et al. [11]	103	61	91	81	79	79
de Paula et al. [12]	611	40	99.3	92.3	88.2	
Stanzione et al. [13] (2016/2017)	166/128*	87.1/81.7	95.9/100	96.4/100	85.4/81.4	91/89.8
Bakkar et al. [10]	52	43	100	100	61	70
Rai et al. [14]	90	83.3	89.4	87.5	85.7	86.5
Meilleroux et al. [5]	299	84.7	92.1	91	86.4	
Rohilla et al. [15]	244	70.5	78.4			71.7
Zare et al. [7]	194	74.5	83.9	62.3	90	81.4
Current study	456	63	92.8	89	73.1	78.5

Table 4. Summary of the ROHMs by diagnostic category using TPSRUC

	Cases, <i>n</i>	NHGUC	AUC	SHGUC	HGUC
<i>ROHM</i>					
de Paula et al. [12]	611	11.1	32.4	64.9	87.9
Stanzione et al. [13]	294	14.4	44.3	88.9	97.4
Bakkar et al. [10]	100	29.7	60.9	100	100
Meilleroux et al. [5]	299	8.7	49	87	91
Rohilla et al. [15]	244	11.6	12.3	33.3	58.8
Wang et al. [6]	167	17.7	50	76.4	89.1
Zare et al. [7]	194	9.9	17.4	72.7	96.3
Hassan et al. [9]	124	15	53	83	100
Pastorello et al. [17] (Mean value weighted by sample size)	–	15.7±7.8	38.5±14.3	76.2±17.2	88.8±12.7
Current study, %	456	17.4	50	81.2	91.3

from 70% to 91%. In accordance with previous research, this study revealed a sensitivity of 63%, specificity of 92.8%, and diagnostic accuracy of 78.5%. The PPV and NPVs were 89% and 73.1%, respectively. Therefore, TPSRUC is a highly specific and accurate reporting system for the detection of HGUC and high-grade malignant neoplasms.

Before TPSRUC was implemented in our institute, a previous study of specimens from our institute [16] showed the risk of high-grade malignancy was 67% in the diagnostic category “suspicious for malignancy or malignant cytology” category. However, this present study showed higher rates of ROHM in the SHGUC (81.2%) and HGUC (91.3%) categories after TPSRUC implementation. The ROHM was significantly increased from 25% in the “atypical cytology” category before TPSRUC implementation to 50% in the AUC category after TPSRUC became the primary system utilization at our institute. Compared with other studies, this present study found higher rates of ROHM in the SHGUC (81.2%) and HGUC

(91.3%) categories (shown in Table 4). In contrast, the AUC rate is comparable to the range of previous studies.

The discordance found in 17 false-positive cases demonstrates the limitations of surgical histological diagnosis due to small nonneoplastic tissue sampling and obscuration by tissue artifacts and inflammation. Danakas et al. [11] have suggested that most false-negative cases are likely to be related to sampling errors.

Several previous studies have focused on false-negative cases, suggesting that false-negative cases result from specimen processing problems due to low cellularity in voided urine [11, 17, 18], poor preservation of the specimen [18], and interpretation issues. These interpretation issues arise from obscuration by inflammation, blood or debris, equivocal cells related to previous treatment, and interpreter error [17, 18]. In our study, 37 false-negative cases occurred in the NHGUC category. Eleven (29.7%) of these were upper urinary tract tumors, 6 (16.2%) were other high-grade tumors involving the urinary bladder, and 8 (21.6%) were paucicellular specimens.

Cytology found 303 (13.9%) AUC samples in this present study. Previous research has found a wide range of AUC from 1.2% to 41.5%, with an average of 10.4%. Only 86 (18.9%) of our AUC specimens had subsequent surgical histology. Half of these (43 cases, 50%) were diagnosed as HGUC and other malignant neoplasms. This rate is approximately comparable to that found in the previous studies, which have rates in the range of 17.4–53%, averaging 32.54%. Other 43 cases were determined in AUC. Of these, 33 (76.7%) were limited by a small number of atypical cells; 2 (4.7%) were caused by inflammation obscuration; and, in the remaining 8, the atypical cells did not fulfill HGUC diagnostic criteria (18.6%).

No LGUN was diagnosed in our urine cytology specimens. However, 55 (12.1%) cases of LGUN were diagnosed histologically after cytological diagnosis of urine in NHGUC (61.8%), AUC (23.6%), SHGUC (3.6%), and HGUC (11%). This low rate of LGUN diagnosis in urine cytology specimens has also been found in previous studies (in samples with histological diagnoses of LGUN, an average of 9% also had a cytological diagnosis of LGUN; range 3.8–53.1%) [17]. In addition, multiple studies that found none or few diagnoses of LGUN on urine cytology subsequently diagnosed LGUN by histopathology [9, 11, 17]. LGUN diagnosed through histopathology was interpreted as NHGUC (average 60%; range 4.5–93.2%) and AUC (average 20%; range 4.2–56.9%) in urine cytology [5, 7, 9, 11, 12, 14, 17]. There were also cytology diagnoses of SHGUC and HGUC in few cases [5, 7, 9, 11, 12, 14, 17]. Owing to the rigid criteria of cellular fragments with fibrovascular cores, diagnosis of LGUN by urine cytology may be limited. A few studies have attempted to define features suggestive of LGUN. These include monotonous intermediate cells and 3-dimensional cellular clusters without fibrovascular cores [5, 11]. In our opinion, these features are somewhat ambiguous means of distinguishing between nonneoplastic tissue and reactive conditions. Further study of low-grade neoplasms may require larger samples to improve cytological criteria for the screening and diagnosis of LGUNs.

Conclusion

Based on this present study of urine cytology diagnosis based on TPSRUC, we advocate the use of TPSRUC in urine cytology examination to detect and monitor HGUC. It produces high specificity (92.8%) and diagnostic accuracy (78.5%). TPSRUC improves the standardization of urine cytology diagnosis, with reproducibility between

interpreters, and accessible diagnosis with good clinical correlations between cytological and histological diagnoses, particularly in AUC cases, in which patients require further investigation and close monitoring.

Statement of Ethics

This study protocol was reviewed and approved by the Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University, with approval number MURA2020/365.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

B.P. contributed to conception and design of the study, collecting and reviewing cases in histopathology, data analysis, and writing manuscript. S.P. (corresponding author) contributed to conception and design of the study, collecting and reviewing cases in urine cytology, data analysis, writing, and critical revision of the manuscript for important intellectual content. J.K. contributed to reviewing histopathology and contributing opinion in discordant cases. J.L. contributed to collecting data in urine cytology. A.P. contributed to reviewing urine cytology and contributing opinion in discordant cases. All authors have read and approved the final version of the manuscript.

Data Availability Statement

All data generated or analyzed during this study are included in this. Further inquiries can be directed to the corresponding author.

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