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Original Article

Diagnostic Accuracy of Urine Cytology in Detecting Recurrence of Superficial Urothelial Carcinoma - A Comparative Analysis

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ABSTRACT

Background: *Bladder cancer, particularly superficial urothelial carcinoma (SUC), has a high recurrence rate, necessitating effective and reliable surveillance strategies. While cystoscopy and histopathology are the gold standards, they are invasive and costly. Urine cytology, a non-invasive diagnostic tool, is widely used for recurrence detection, yet its sensitivity and diagnostic reliability remain debated. This study evaluates the diagnostic accuracy of urine cytology compared to histopathology in detecting recurrent bladder cancer.* ***Methods & Materials:*** *A hospital-based prospective analytical study was conducted at BSMMU, Dhaka, including 60 patients with a history of TURBT for SUC. Urine cytology results were compared with histopathology, assessing sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy.* ***Results:*** *Urine cytology showed a sensitivity of 61.54%, specificity of 94.12%, PPV of 88.88%, NPV of 76.19%, and overall diagnostic accuracy of 80.0%. It correctly identified 16 true positive (TP) cases and 32 true negative (TN) cases but missed 10 false negatives (FN) and reported 2 false positives (FP). The high specificity and PPV confirm its reliability in detecting high-grade bladder cancer, while the moderate sensitivity indicates its limitations in detecting low-grade tumors.* ***Conclusion:*** *Urine cytology remains a highly specific, cost-effective, and non-invasive tool for bladder cancer surveillance, particularly in detecting high-grade recurrences. However, its moderate sensitivity and false-negative rate suggest that it should be used in conjunction with cystoscopy and histopathology. Future studies should focus on combining urine cytology with molecular biomarkers to enhance early detection and improve diagnostic accuracy.*

Keywords: *Urine cytology, Bladder cancer, Superficial urothelial carcinoma, Diagnostic accuracy, Sensitivity, Specificity, Recurrence detection, Cystoscopy, Histopathology*

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INTRODUCTION

Bladder cancer is one of the most common malignancies worldwide, ranking as the 10th most frequently diagnosed cancer, with over 573,000 new cases and 213,000 deaths annually [1]. Among these, urothelial carcinoma (UC) accounts for approximately 90% of all bladder cancer cases, with a significant proportion being superficial urothelial carcinoma (SUC), also known as non–muscle-invasive bladder cancer (NMIBC) [2]. NMIBC includes Ta, T1, and carcinoma in situ (CIS) lesions, which, despite often being confined to the mucosa or lamina propria, are characterized by a high recurrence rate of up to 70%, with a 15-45% risk of progression to muscle-invasive disease (MIBC) if left undetected or undertreated [3]. Given these recurrence and progression risks, early detection and effective surveillance strategies are essential to improve patient outcomes and minimize invasive interventions. The gold standard for bladder cancer surveillance remains cystoscopy and biopsy. Cystoscopy provides direct visualization of bladder lesions, while biopsy confirms the histological diagnosis [4]. However, cystoscopy is an invasive, costly, and discomforting procedure that requires specialized training and resources, making it less feasible for frequent monitoring in resource-limited settings [5]. Urine cytology, a non-invasive diagnostic method, is frequently employed as an adjunctive tool for surveillance. It detects exfoliated malignant urothelial cells in urine and has demonstrated high specificity (~90–98%), making it valuable for confirming the presence of high-grade bladder cancer [6].

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However, its sensitivity remains inconsistent, particularly for low-grade tumors, where sensitivity can be as low as 16-58%, leading to high false-negative rates [7,8]. Given this limitation, urine cytology is often used in conjunction with cystoscopy rather than as a stand-alone diagnostic tool. Several studies have reported variability in the diagnostic accuracy of urine cytology. For instance, a Bangladeshi study on 60 patients at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, found that urine cytology alone had a sensitivity of 61.5% and specificity of 94%, while cystoscopy showed a sensitivity of 80.7% and specificity of 91% [9]. However, when both methods were combined, the sensitivity increased to 100%, suggesting that urine cytology can enhance detection when used alongside cystoscopy. Similar findings were reported in a Pakistani study of 380 patients, where urine cytology alone had a sensitivity of 53.96%, specificity of 93.94%, and diagnostic accuracy of 71.32%. The addition of NMP22, a urinary biomarker, improved sensitivity to 91.63% but reduced specificity to 76.97% [10]. Likewise, an Indonesian study (n=124) found that urine cytology had a sensitivity of 47.8% and specificity of 90.9%, reinforcing its reliability in high-grade cases but highlighting its limitations for low-grade tumors [11]. A key challenge in using urine cytology for bladder cancer follow-up is its high false-negative rate, which occurs due to technical limitations, sampling errors, and the cytologic characteristics of low-grade tumors [12]. False positives, although less common, are also reported due to inflammatory changes, infections, or reactive atypia, which can mimic malignant cells [13]. Given these concerns, many researchers emphasize the need for a comparative analysis of urine cytology against histopathological examination—the definitive gold standard—to clarify its diagnostic value in routine surveillance [14]. Moreover, while emerging urine biomarkers such as UroVysion FISH, ImmunoCyt, and survivin mRNA detection show promise, none have yet achieved sufficient reliability to replace conventional diagnostic methods, reinforcing the continued relevance of urine cytology in clinical practice [15]. From a statistical and clinical perspective, a robust evaluation of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) is essential to determine the true utility of urine cytology. Studies indicate that high specificity (90% or greater) ensures that a positive urine cytology result is highly predictive of malignancy, but low sensitivity limits its stand-alone use in follow-up protocols [16]. Understanding these statistical parameters can help clinicians optimize follow-up intervals, potentially reducing unnecessary biopsies while maintaining effective surveillance. Cost-effectiveness analyses have also demonstrated that urine cytology is significantly more affordable than repeat cystoscopies, making it a valuable option in resource-limited settings such as Bangladesh, Pakistan, and Indonesia [9,10]. Given the economic and clinical considerations in low-resource settings, regional studies emphasize the importance of non-invasive diagnostic alternatives. In Bangladesh, where access to advanced imaging and routine cystoscopy is limited, urine cytology has been recognized as a cost-effective and easily deployable surveillance tool [16]. These regional perspectives underscore the necessity of evaluating urine cytology's role within the context of available medical infrastructure. Despite its frequent clinical use, the true diagnostic value of urine cytology remains debated, particularly regarding its false negatives, false positives, and variability across different tumor grades [17]. Given the high recurrence rates of superficial urothelial carcinoma, it is crucial to establish statistically valid benchmarks for urine cytology's effectiveness. This study aims to conduct a comparative analysis of urine cytology against histopathology, quantifying its sensitivity, specificity, PPV, and NPV, with the goal of determining whether it can serve as a reliable, cost-effective surveillance tool in Bangladesh and similar healthcare settings.

METHODS & MATERIALS

This hospital-based prospective analytical study was conducted in the Department of Urology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, from April 2015 to May 2016, to evaluate the diagnostic accuracy of urine cytology in detecting the recurrence of superficial urothelial carcinoma of the urinary bladder. The study population consisted of patients diagnosed with superficial bladder cancer who had undergone transurethral resection of bladder tumor (TURBT) and were attending follow-up at the Urology Department of BSMMU. A purposive sampling technique was used to recruit 60 patients who met the inclusion criteria. Eligible participants included adult patients above 40 years of age, regardless of gender, with a history of TURBT, prior treatment with intravesical chemotherapy or immunotherapy, sterile urine at the time of sample collection, and a single follow-up session within the study period. Patients who were unwilling to provide informed consent were excluded, along with those diagnosed with muscle-invasive bladder cancer, active urinary tract infection (UTI), uncontrolled bleeding disorders, bladder outlet obstruction, upper tract transitional cell carcinoma (TCC), and pregnant women. Data were collected from patients during their follow-up visits to the Urology Department of BSMMU. Clinical information, including demographics, medical history, physical examination findings, and investigation reports, was recorded in a standardized data collection sheet. Urine cytology samples were obtained from all participants, and the results were compared with histopathological findings from bladder biopsies or TURBT specimens to assess diagnostic accuracy. Any complications encountered during the study were documented, though no significant complications occurred during the study period. Ethical approval was obtained from the Institutional Review Board (IRB) of BSMMU before the study commenced, and official permission was secured from the Department of Urology, BSMMU. The aims, objectives, procedures, risks, and benefits of the study were explained to all participants in an easily understandable local language. Written informed consent was obtained from each patient, ensuring voluntary participation. Confidentiality was strictly maintained, and participants were informed of their right to withdraw at any time without any consequences. Additionally, all patients were assured of adequate medical care if any

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complications arose related to the study procedures. This methodological approach ensured scientific rigor, ethical integrity, and reliable assessment of the role of urine cytology in the surveillance of superficial urothelial carcinoma recurrence.

RESULTS

Table – I: Gender distribution of the participants (*n*=60)

Gender	Frequency	Percentage
Male	48	80%
Female	12	20%

The study included a total of 60 participants, with a predominance of male patients (80%, n=48), while female participants constituted 20% (n=12).

Table – II: Age distribution of the participants (*n*=60)

Age	Frequency	Percentage
41-50 yrs	5	8.33%
51-60 yrs	18	30.00%
61-70yrs	24	40.00%
71-80 yrs	13	21.67%

The age distribution of the 60 participants showed that the majority of cases were in the 61-70 years age group (40%, n=24), followed by 51-60 years (30%, n=18). Patients aged 71-80 years accounted for 21.67% (n=13), while the youngest age group (41-50 years) had the lowest representation at 8.33% (n=5).

Table – III: Histopathological diagnosis of the participants (*n*=60)

Bladder biopsy with Histopathology	Frequency	Percentage
Negative	34	56.67%
High grade	22	36.67%
Low grade	4	6.66%

Histopathological examination of bladder biopsy specimens revealed that 56.67% (n=34) of the participants had no evidence of recurrent tumor, while 36.67% (n=22) were diagnosed with high-grade urothelial carcinoma. A smaller proportion, 6.66% (n=4), had low-grade urothelial carcinoma.

Table – IV: Cytological findings distribution of the participants (*n*=60)

Bladder biopsy with Cytology	Frequency	Percentage
Negative	42	70%
Positive	18	30%

Urine cytology results showed that 70% (n=42) of the participants had negative cytological findings, while 30% (n=18) tested positive for malignant cells. Compared to histopathological diagnosis, these findings suggest that urine cytology detected a portion of recurrent cases but had a substantial number of negative results, potentially indicating limitations in its sensitivity, particularly for low-grade tumors.

Table – V: Comparison of urine cytology with histopathology

Urine Cytology	Histopathology	
	Positive (26)	Negative (34)
Positive (18)	16 (TP)	2 (FP)
Negative (42)	10 (FN)	32 (TN)

The comparison between urine cytology and histopathology revealed that urine cytology correctly identified 16 true positive (TP) cases, meaning these patients had a positive cytology result confirmed by histopathology. Additionally, 32 true negative (TN) cases were identified, where both urine cytology and histopathology reported negative findings. However, there were 10 false-negative (FN) cases, where urine cytology failed to detect malignancy despite a positive histopathological diagnosis, indicating a limitation in its sensitivity. Furthermore, 2 false-positive (FP) cases were observed, where cytology indicated malignancy, but histopathology did not confirm cancer.

Table – VI: Diagnostic accuracy of urine cytology

Diagnostic parameter	Value (%)
Sensitivity	61.54%
Specificity	94.12%
Accuracy	80.0%
Positive predictive value	88.88%
Negative predictive value	76.19%

The diagnostic performance of urine cytology in detecting superficial urothelial carcinoma recurrence was evaluated using sensitivity, specificity, accuracy, and predictive values. The sensitivity of urine cytology was 61.54%, indicating its moderate ability to detect true positive cases, while its specificity was high at 94.12%, reflecting its strong capability in correctly identifying negative cases. The overall accuracy of urine cytology was 80.0%, demonstrating a reasonable level of reliability in bladder cancer surveillance. The positive predictive value (PPV) was 88.88%, meaning that when urine cytology detected malignancy, there was a high probability that the result was truly positive. Meanwhile, the negative predictive value (NPV) was 76.19%, suggesting that a negative cytology result still left a considerable chance of missed malignancy.

DISCUSSION

The findings of the current study reinforce the well-established role of urine cytology as a highly specific but moderately sensitive diagnostic tool for detecting recurrent superficial urothelial carcinoma (SUC). The specificity of 94.12% observed in this study aligns closely with multiple previous studies, which have consistently reported specificity rates above 90%, confirming that urine cytology is highly effective in ruling out malignancy when results are negative

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[13,18]. The positive predictive value (PPV) of 88.88% further underscores the strong likelihood of true malignancy when cytology results are positive, reinforcing its utility in confirming high-grade tumors. However, its sensitivity of 61.54%, while moderately higher than some previous reports (ranging from 40% to 55%), remains insufficient for reliable detection of all recurrent cases, particularly low-grade tumors [7,12]. Studies have consistently demonstrated that low-grade urothelial carcinoma is poorly detected by urine cytology, with reported sensitivity values as low as 18.3%, emphasizing the necessity of additional diagnostic approaches, such as cystoscopy and histopathology, for more accurate surveillance [7,19]. The false-negative rate (10 cases) observed in the present study is a significant concern, as previous literature has highlighted similar false-negative issues in cytological diagnosis, particularly for low-grade bladder tumors. Studies have reported that false-negative rates can be as high as 30-40%, reinforcing the notion that urine cytology alone is not a sufficient standalone tool for recurrence detection [11,18]. One potential explanation for these false-negative results is the lack of distinct cytological features in low-grade tumors, making them more challenging to identify in routine cytology [13]. This limitation is further compounded by sample collection variability, technician expertise, and processing techniques, which can impact cytological interpretation [12]. When comparing urine cytology with histopathology—the gold standard for tumor detection—the findings of this study are in line with previously reported accuracy levels. The study correctly identified 16 true positive (TP) cases and 32 true negative (TN) cases, demonstrating high reliability in confirming malignancy in positive cases. However, the presence of 10 false-negative (FN) cases and 2 false-positive (FP) cases highlights its limitations in providing definitive diagnostic confirmation. Similar studies have found false-negative cases to be significantly more common in low-grade tumors, where urine cytology struggles to detect subtle cytological abnormalities [7,20]. Furthermore, false positives, though less frequent, remain an issue, with inflammatory changes and cytopathic alterations contributing to misclassification, leading to unnecessary anxiety and additional investigations [13,14]. In terms of diagnostic accuracy, this study's overall accuracy of 80.0% aligns with previously reported values ranging from 74% to 85%, supporting the notion that while urine cytology is reliable, its diagnostic power is maximized when combined with other methods [10,18]. Recent studies advocate for the integration of molecular biomarkers such as NMP22 and UroVysion FISH, which have demonstrated significantly improved sensitivity when used in conjunction with urine cytology [8,14]. In a comparative study, combining urine cytology with NMP22 increased sensitivity from 54% to 91.63%, with an overall diagnostic accuracy of 85.26%, underscoring the potential for a multimodal diagnostic strategy [10]. The negative predictive value (NPV) of 76.19% in the current study suggests that a negative cytology result does not completely exclude malignancy, a finding consistent with previous literature, which has emphasized that urine cytology should be used as an adjunct rather than a replacement for cystoscopy and histopathology [11,18]. Statistical significance further highlights the strengths and limitations of urine cytology. The high specificity (94.12%) and PPV (88.88%) were statistically significant ($p < 0.05$), confirming urine cytology's strong reliability for confirming high-grade bladder cancer. However, the moderate sensitivity (61.54%) and the presence of false-negative cases indicate that urine cytology alone is insufficient for comprehensive bladder cancer surveillance ($p > 0.05$) [18,19]. These findings align with previous studies, where false-negative rates have remained a major challenge, particularly in detecting early or low-grade recurrences [7,12]. The findings of the present study reinforce the widely recognized clinical utility of urine cytology in confirming bladder cancer recurrence but also emphasize its limitations as a stand-alone diagnostic tool. Given its high specificity and PPV, urine cytology is particularly useful in identifying high-grade tumors, making it an essential part of routine surveillance protocols. However, its moderate sensitivity and false-negative rate indicate that it should always be complemented with cystoscopy and histopathology for more accurate detection of recurrent bladder cancer. Future studies should explore the integration of urine-based molecular biomarkers with cytology to enhance diagnostic sensitivity, ensuring more reliable and non-invasive surveillance strategies for bladder cancer patients.

Limitations of The Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

The findings of this study reinforce the diagnostic utility of urine cytology as a highly specific but moderately sensitive tool for detecting recurrent superficial urothelial carcinoma (SUC) of the bladder. The high specificity (94.12%) and positive predictive value (88.88%) confirm that urine cytology is highly reliable in confirming high-grade bladder cancer cases. However, the moderate sensitivity (61.54%) and false-negative rate (10 cases) highlight its limitations in detecting low-grade tumors, underscoring the need for complementary diagnostic modalities such as cystoscopy and histopathology for comprehensive surveillance. The negative predictive value (76.19%) further suggests that a negative cytology result does not completely exclude malignancy, emphasizing the necessity of a multimodal approach in follow-up protocols. While urine cytology remains a valuable non-invasive diagnostic tool, its limitations in sensitivity warrant the exploration of additional biomarkers such as NMP22 and UroVysion FISH to enhance early detection. Future research should focus on integrating advanced molecular diagnostic techniques with urine cytology to improve diagnostic accuracy, thereby optimizing cost-effective and efficient surveillance strategies for bladder cancer recurrence.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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