Correlations between Routine Urinalysis and Cystoscopy for the Diagnosis of Urinary Bladder Invasion in Patients with Cervical Cancers

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Background: *Cystoscopy is a study recommended in patients with cancer of cervix uteri (CC) to evaluate for urinary bladder invasion (BI). However, yield of the study in early-stage CCs is very low, leading a search to find a less invasive test that would help select patients with higher priority to undergo cystoscopy.*

Objective: *To determine clinical correlations between the screening urinalysis (UA) and cystoscopy for the diagnosis of BI in patients with CC.*

Material and Method: *Medical records from the electronic database of CC patients treated in Songklanagarind Hospital between 2004 and 2013 were reviewed. All newly diagnosed CCs were scheduled for a cystoscopy to evaluate for BI. Those who had a UA sent within 100 days of cystoscopy were included. Data including patients' age, stage at diagnosis, type of treatment received, and UA profiles were analyzed for their correlations with the cystoscopic results.*

Results: *Eight hundred seventy five cases were included in the analysis. Mean duration from diagnosis of CC to cystoscopy was 167 days. Cystoscopies were performed before treatment in only 238 cases (27.4%). The cystoscopic results reported negative study in 791 cases (90.4%). Among the cases with positive findings, 23 cases (2.6%) had BI, while the majority had chronic cystitis (6.7%). Tumor stages (III to IV), and time from diagnosis to do cystoscopy (those performed before treatment initiation) were associated with higher BI positivity rates. The UA parameters that were significantly associated with BI included proteinuria, bilirubinuria, nitrisuria, hematuria, and positive urine leukocytes. On multiple logistic regressions, proteinuria, and nitrisuria were the two parameters independently associated with BI at the OR 6.49 (95% CI 1.81 to 23.22) and 3.77 (95% CI 1.17 to 12.07), respectively. When the two parameters were considered together with the pre-cystoscopy status, the analysis showed that proteinuria and nitrisuria increased in the incidence of BI from 5% to 20 to 30% and 30% to 60 to 100% of stage III and IV cervical cancer, respectively.*

Conclusion: *Routine practice of cystoscopy in CC should be re-considered. As the yield is very low, the study might be avoided in early stages. Priority should be given to those with stage III and IV, especially when protein and nitrite are positive in the UA.*

Keywords: *Cervical cancer, Urinary bladder invasion, Urinalysis, Cystoscopy*

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Cystoscopy is a recommended investigation in patients with cancer of the cervix uteri (CC) to evaluate for urinary bladder invasion (BI)[1]. The diagnosis is usually made by endoscopic demonstration of bladder wall involvement. As suggested by the expert opinions, biopsy must be done when any bladder lesion is found during cystoscopy[2,3]. According to The International Federation of Gynecology and Obstetrics (FIGO) staging system, patients with advanced stage disease (stage IIB and higher) are highly potential to develop BI; while in early-stage disease (stages I through IIA), the risk is substantially low[4-7]. For this reason, routine cystoscopy is not required if BI is not suspicious by clinical staging. In our institute, all newly diagnosed CCs were scheduled for cystoscopy to rule out BI. The operations were scheduled as soon as possible, and depended on the availability of the operating rooms. Since there are no criteria to classify patients who need the more urgent procedure, the duration from diagnosis to cystoscopy is unpredictable. As a result, a number of patients had been treated, either by surgery or radiotherapy before staging cystoscopy

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was done. The authors hypothesized that if there was any less invasive test that help selecting patients with higher priority to undergo cystoscopy. Urinalysis (UA) is a routine screening test for hematuria that may contribute further information related to BI; however, inflammatory conditions such as cystitis may be accompanying(8). The aim of the present study was to determine clinical correlations between the screening UA and cystoscopy for the diagnosis of BI in patients with cervical cancer.

Material and Method

Medical records from the electronic database of CC patients treated at the Songklanagarind Hospital between January 2004 and December 2013 were reviewed. The study was approved by the Institutional Review Board (IRB) of Songklanagarind Hospital Ethic Committee. All newly diagnosed CCs who underwent cystoscopy for BI evaluation and had sent UA within 100 days before or after cystoscopy were included in the present study. Patients were excluded if they had cystoscopy due to hematuria, abnormal voiding symptoms, or a suspicion of recurrence after complete remission. Patients with inadvertent diagnosis or incomplete staging were also excluded. Demographic data of all patients including age, stage at diagnosis, and type of treatment received were accumulated. Calculation of sample size used data from previous studies[9,10] that reported prevalence of BI at 2.8% to 3.1% of all cervical cancers. Taken estimated sensitivity and specificity of UA were at 90% together with minimal acceptable lower confidence limit at 0.8, the study required at least 235 patients to analyze for accuracy[11].

Cystoscopic results were acquired from the operative reports, out-patient records or progress notes from the computer database. If cystoscopy was performed previously more than once, we used only the first procedure performed to evaluate for BI for the analysis. Cystoscopic results were categorized into three groups, 1) cystitis and related inflammatory conditions, 2) a suspicion of tumor invasion, and 3) other bladder abnormalities. Cystitis and related inflammatory conditions were determined by any operative documentations of bullous edema, mucosal swelling, redness, inflammation, hemorrhage, ulceration, trabeculation, or telangiectasia[12,13]. For the cases whom tumor invasion was suspected, we did further exploration to ascertain that if biopsy had been done and what was the pathological report. Other bladder abnormalities were considered if cystoscopies identified any findings that were not tumors and did not meet the cystitis criteria. Lesions of the urethra and ureteral orifices were not completely evaluated.

The UA was collected in the time between diagnosis and cystoscopy. If a patient had more than one UA profile, we chose the one collected on the date closed to cystoscopy. If not available, we chose the one obtained at the date closed to diagnosis instead. If none of them were available, we then alternatively used the one that collected at the time between the date of diagnosis and cystoscopy. Acceptable urine specimens must be taken less than 100 days from either of the date of diagnosis or cystoscopy. Finally, we defined the UA profiles as UA near cystoscopy or UA near diagnosis depended on the closer duration of UA-to-cystoscopy or UA-to-diagnosis, respectively. The UA parameters we used for the analysis included protein, glucose, ketone, bilirubin, urobilinogen, nitrite, red blood cells, and leukocytes. The values of each parameter were recorded according to the hospital laboratory reference.

To figure out if the treatment received affected the UA results and cystoscopic findings, we designated either pre- or post-treatment status to the UA and cystoscopy. This was based on the date of treatment beginning compared with the dates of UA collection and cystoscopy. The method of treatment for each patient was also noted.

The data were formulated by using a spreadsheet template in Microsoft Excel. Disease stages were simplified into stage I, II, III, and IV. Demographic data were tabulated as mean, sum and percentile. Corresponding factors including stage at diagnosis, timings of UA collection and cystoscopy, pre- and post-treatment statuses, treatment methods, and the UA parameters were evaluated for their correlations with the cystoscopic results by means of univariate and multivariate regression analyses. Statistical significance for each correlation were estimated with 95% confidence interval and *p*-value of 0.05 or less. In addition, we also calculated the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy for each UA parameters that were associated with BI positivity. Statistical calculation used Stata program version 13.1 (Stata Corporation, TX, USA).

Results

Demographic data

Eight hundred seventy five cervical cancer cases that underwent cystoscopies to evaluate for BI

during the study period were included in the analysis. Mean age was 53.1 years (range 24.7 to 86.2 years). Stage distributions were stage 0 (carcinoma in-situ) four cases (0.5%), stage I 121 cases (13.8%), stage II 464 cases (53.0%), stage III 258 cases (29.5%), and stage IV 28 cases (3.2%). Mean duration from diagnosis to cystoscopy was 167 days (range 1 to 1,347 days). Cystoscopies were performed before treatment initiation in only 238 cases (27.4%). Of the 637 cases that had cystoscopy after treatment, the treatment methods consisted of surgery in 47 cases, surgery followed by radiation therapy in 24 cases, and radiation alone in 564 cases.

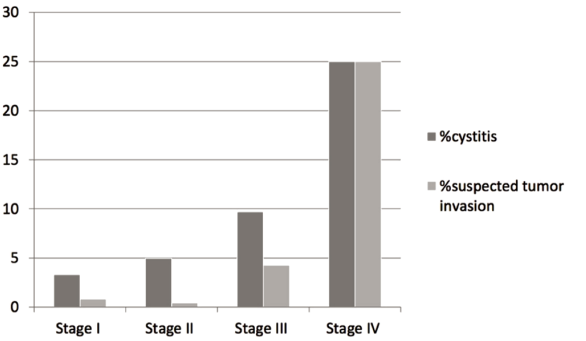

Fig. 1 Incidences of 2 main positive findings on cystoscopy based on tumor stages (%).

Cystoscopic results

The cystoscopy reported negative study in 791 cases (90.4%). Among the cases with positive results, 59 cases (6.7%) had cystitis and related inflammatory conditions, 21 cases (2.4%) were suspected to have tumor invasion, and four cases (0.5%) had other conditions including two cases of bladder diverticulum, one case of vesicovaginal fistula, and one case of non-specific ulceration. The incidences of cystitis and a suspicion of tumor invasion were significantly increased with tumor stages (Chi-square, *p*-value <0.01) (Fig. 1). Endoscopic biopsies were performed only in seven cases that included two cases in the cystitis group, four cases in the tumor suspicion group, and one case of mucosal ulceration. Of 21 cases with cystoscopic findings of tumor invasion, tissue biopsy was not performed in 17 cases. The pathological studies reported positive cervical cancer in three cases, one in those suspected to have tumor invasion and two in those who had atypical inflammation.

When the 21 cases who had tumor suspicion were grouped together with the two cases of inflammation and histologically positive for carcinoma, 23 cases were considered as positive urinary BI. On univariate analysis, the two factors correlated with BI were tumor stages and timing of cystoscopy. As illustrated in Table 1, the patients with stage III to IV were associated with higher risks of having BI (odds ratio 14.69, 95% CI 4.33 to 49.85) and cystoscopies that performed after treatment initiation were significantly associated with lower BI positivity rates (odds ratio 0.33, 95% CI 0.14 to 0.76).

Table 1. Factors associated with cystoscopic positivity

Parameter	Odds ratio	95% CI	*p*-value
Stage III to IV	14.69	4.33 to 49.85	<0.001*
Age >40 years	3.54	0.47 to 26.49	0.220
Cystoscopy after treatment	0.33	0.14 to 0.76	0.009

* 95% confidential interval (CI)

UA and positive BI

Among parameters within the UA profiles, five parameters were significantly associated with BI including proteinuria, bilirubinuria, nitrisuria, microscopic hematuria, and positive urine leukocytes (Table 2). On multiple logistic regression, proteinuria, and nitrisuria were the two parameters independently associated with BI at the OR 6.49 (95% CI 1.81 to 23.22) and 3.77 (95% CI 1.17 to 12.07), respectively.

Considering the effect of treatment on the diagnostic capability of UA, a comparison capability of UA, a comparison was made between the UA collected before and after treatment initiation. It was demonstrated that UA before treatment gave better correlations with BI, in terms of the *p*-value and the precision (Table 3).

When a comparison was made between the UA collected at the time near diagnosis and near cystoscopy, it was found that UA near cystoscopy gave better correlation with BI than UA near diagnosis (Table 4).

Incidence of BI based on combined parameters

To evaluate the possibility to apply the urine parameters in a prioritization of cervical cancer patients for cystoscopy, the two independent parameters were considered together with the pre-cystoscopy stage. The analysis had shown that if UA of cervical cancer patient found proteinuria with nitrisuria increase incidence of BI from 5% to 20 to 30% in stage III, and from 30% to 60 to 100% in stage IV (Fig. 2).

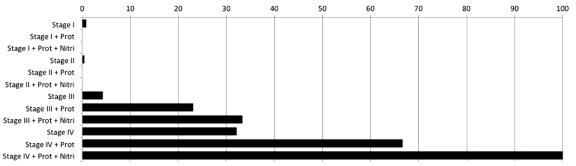

Fig. 2 Incidences of bladder invasion according to stage, with and without combination with urine parameters.

Discussion

Cystoscopy and sigmoidoscopy, previously categorized as mandatory investigations, were reclassified as optional investigations in a recent revision of FIGO staging[14]. Since the 2009 revision of FIGO staging, a few studies have explored the identification of patients who will need endoscopy[5,9].

In our institute, cystoscopy is routinely performed in all newly diagnosed cervical cancer patients to screen for BI. The present study demonstrated that most of the patients in the analysis had negative cystoscopic results. In addition, the majority of patients with positive cystoscopy had only cystitis or inflammation. As we performed the analysis to each stage, it was found that the prevalence of abnormal finding of cystoscopy to screen for BI was remarkably low in the early-stages when compared to those with stages III/IV. This is consistent with the recent guidelines recommend cystoscopy to perform in only patients with clinically suspicion[1].

However, to apply the results of the present study to general practice, it is important to specify the appropriate timing of cystoscopy. According to our data, cystoscopies were performed at an average 167 days after the diagnosis of cervical cancer. This might be delayed for the staging of newly diagnosed CC patients. Additionally, cystoscopies were performed

Table 2. Urine parameters that were significantly associated with bladder invasion (BI) as evidenced by cystoscopy and/or pathological diagnosis

Parameter	+LHR (%) (95% CI)	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	PPV (%) (95% CI)	NPV (%) (95% CI)	Accuracy (%)
Proteinuria (≥3+)	9.75 (3.99 to 23.83)	21.7 (7.5 to 43.7)	97.7 (96.5 to 98.7)	20.8 (9.70 to 39.1)	97.9 (97.4 to 98.3)	95.8
Bilirubinuria (≥2+)	9.26 (2.08 to 41.20)	8.7 (1.07 to 28.0)	99.1 (98.2 to 99.6)	20.0 (2.52 to 55.6)	97.6 (96.3 to 98.5)	96.7
Nitriuria	5.42 (2.56 to 11.50)	26.1 (10.2 to 48.4)	95.2 (93.5 to 96.5)	12.8 (4.83 to 25.7)	97.9 (96.7 to 98.8)	96.7
RBC (>50 cells/HPF)	2.52 (1.61 to 3.94)	47.8 (26.8 to 69.4)	81.0 (78.2 to 83.6)	6.36 (3.22 to 11.1)	98.3 (97.0 to 99.1)	80.1
WBC (>50 cells/HPF)	3.50 (1.82 to 6.75)	30.4 (13.2 to 52.9)	91.3 (89.2 to 93.1)	8.64 (3.55 to 17.0)	98.0 (96.7 to 98.8)	89.7

+LHR = positive likelihood ratio; PPV = positive predictive value; NPV = negative predictive value; RBC = red blood cell; WBC = white blood cell; HPF = high-power field

Table 3. Comparing odds ratio, 95% CI, and *p*-value of each urinalysis (UA) parameter for the diagnosis of bladder invasion (BI) based on treatment received

Parameters	Odds ratio	95% CI	*p*-value
UA before treatment (n = 512)			
Proteinuria (>3+)	12.44	3.53 to 43.78	<0.001
Bilirubin (>2+)	14.09	2.51 to 78.95	0.003
Nitrite	6.62	2.17 to 20.21	0.001
RBC (>50 cells/HPF)	3.22	1.18 to 8.82	0.023
WBC (>50 cells/HPF)	4.69	1.56 to 14.11	0.006
UA after treatment (n = 363)			
Proteinuria (>3+)	9.67	1.00 to 93.15	0.050
Nitrite	NA	-	-
Bilirubin (>2+)	6.39	0.70 to 58.71	0.101
RBC (>50 cells/HPF)	6.68	1.22 to 36.59	0.029
WBC (>50 cells/HPF)	4.32	0.80 to 23.22	0.088

NA = not applicable

Table 4. Correlations of UA and BI based on timing of urine specimen collection between UA near diagnosis and near cystoscopy

Parameters	Odds ratio	95% CI	*p*-value
UA near diagnosis (n = 231)			
Proteinuria (>3+)	4.41	0.48 to 40.85	0.192
Bilirubin (>2+)	NA	NA	NA
Nitrite	2.51	0.406	0.406
RBC (>50 cells/HPF)	4.55	0.046	0.046
WBC (>50 cells/HPF)	1.20	0.185	0.185
UA near cystoscopy (n = 644)			
Proteinuria (>3+)	18.70	5.20 to 67.18	<0.001
Nitrite	13.67	2.59 to 72.23	0.020
Bilirubin (>2+)	10.34	3.32 to 33.23	<0.001
RBC (>50 cells/HPF)	4.14	1.48 to 11.63	0.007
WBC (>50 cells/HPF)	1.34	1.11 to 1.61	0.002

after treatment in 73% of patients; as a consequence, the diagnosis of early BI in these patients might be precluded. Since cystoscopies after treatment provided significantly lower BI positivity rate, it is crucial that the operation must be performed before treatment start.

As we used UA to screen for patients who were more likely to have BI. We found the associations of proteinuria and nitrisuria with the higher rates of positive cystoscopy. However, one of the limitations of the present study was the variation of the timing of urine specimen collection. As such a number of patients had multiple UA profiles; therefore, we categorized the UA based on timing of urine collection and treatment received, and verified whether both factors influenced the association with cystoscopy. The analysis showed that a UA was good correlated with the cystoscopic results when it was done near the study and before the cervical cancer treatment. However, using UA near cystoscopy to allocate patients might be not practical. It is ideal to collect UA on the day of diagnosis when cystoscopy could be scheduled soon after. Another limitation of our study was the lack of biopsy in most of the patients who had tumor suspicion. The diagnoses of BI in those cases were determined only by the cystoscopic findings.

According to our data, the yield of cystoscopy was very low, particularly in the early-stages and post-treatment cases. Our practice of routine cystoscopy in the CC patients should be revolutionized. If the waiting time is too long, the procedure should be prioritized to those with higher chance to have benefit from the study. However, further prospective studies should be conducted to determine the more accuracy of UA to predict the possibility of having BI.

Conclusion

Routine practice of a cystoscopy in CC should be re-considered. As the yield was very low, the study might be exempted in early stages. Priority should be given to those with stage III/IV, especially when protein and nitrite were positive in the UA.

What is already known on this topic?

Cystoscopy is a routine practice for cervical cancer staging. Evaluation of BI, because of local invasion of cervical cancer, can occur in bladder and rectum. However, benefit of this procedure was reconsidered due to BI from early stages cervical cancer was low in our practice.

What this study adds?

From yield of the present study, cystoscopy in early-stage CCs is very low, leading to the question if there was any less invasive test that help selecting patients with higher priority to undergo cystoscopy. This study showed clinical correlations between the screening UA, and cystoscopy for the diagnosis of BI in CC patients. In our study concluded that routine practice of cystoscopy in CC should be re-considered. As the yield was very low, the study might be avoided in early stages CC. Priority should be given to those with stage III/IV, especially when protein and nitrite were positive in the UA.

Potential conflicts of interest

None.

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ผลการศึกษาความสัมพันธ์ระหว่างผลการตรวจปัสสาวะกับการส่องกล้องกระเพาะปัสสาวะในการวินิจฉัยการกระจายเข้ากระเพาะปัสสาวะในผู้ป่วยมะเร็งปากมดลูก

ธนัญญ์ เพชรานนท์, วรพล รัตนเลิศ, จิตติ หาญประเสริฐพงษ์, สุรศักดิ์ สังขทัต ณ อยุธยา, วาทิต กาญจนวนิชกุล, มณฑิรา ตัณฑนุช, ชูศักดิ์ ปริพัฒนานนท์

ภูมิหลัง: *การส่องกล้องกระเพาะปัสสาวะเป็นข้อบ่งชี้ในการประเมินระยะการแพร่กระจายของโรคมะเร็งปากมดลูก เพื่อดูการกระจายเข้ากระเพาะปัสสาวะ แต่ในทางปฏิบัติพบว่าการส่องกล้องกระเพาะปัสสาวะทุกรายพบความผิดปกติน้อยมาก*

วัตถุประสงค์: *ศึกษาความสัมพันธ์ระหว่างการคัดกรองด้วยการตรวจปัสสาวะและการส่องกล้องกระเพาะปัสสาวะในการประเมินการกระจายเข้ากระเพาะปัสสาวะในผู้ป่วยมะเร็งปากมดลูก*

วัสดุและวิธีการ: *เก็บข้อมูลจากฐานข้อมูลผู้ป่วยมะเร็งปากมดลูกที่รักษาในโรงพยาบาลสงขลานครินทร์ตั้งแต่ พ.ศ. 2547 ถึง พ.ศ. 2556 โดยเลือกผู้ป่วยมะเร็งปากมดลูกที่ถูกวินิจฉัยใหม่ และได้รับการตรวจด้วยการส่องกล้องกระเพาะปัสสาวะเพื่อประเมินการแพร่กระจายเข้ากระเพาะปัสสาวะ และใช้ข้อมูลการตรวจปัสสาวะก่อนหรือหลังส่องกล้องกระเพาะปัสสาวะในช่วง 100 วัน ทำการเก็บข้อมูลทั่วไปผู้ป่วย อายุ ระยะของโรคมะเร็ง ชนิดของการรักษา และผลการตรวจปัสสาวะ หลังจากนั้นทำการวิเคราะห์ข้อมูลหาความสัมพันธ์ระหว่างข้อมูลข้างต้นกับผลการส่องกล้องกระเพาะปัสสาวะ*

ผลการศึกษา: *ผู้ป่วยทั้งหมด 875 ราย ระยะเวลาเฉลี่ยจากการวินิจฉัยจนถึงวันที่ส่องกล่องเฉลี่ย 167 วัน ได้รับการส่องกล้องกระเพาะปัสสาวะก่อนรับการรักษา 238 ราย หรือ ร้อยละ 27.4 จากการส่องกล้องกระเพาะปัสสาวะพบว่าไม่มีความผิดปกติของกระเพาะปัสสาวะสูงถึง 791 ราย หรือ ร้อยละ 90.4 ส่วนกลุ่มที่พบความผิดปกติ พบว่ามีการแพร่กระจายของมะเร็งปากมดลูกเข้ากระเพาะปัสสาวะ 23 ราย หรือ ร้อยละ 2.6 และเป็นกระเพาะปัสสาวะอักเสบเรื้อรังร้อยละ 6.7 ในกลุ่มที่เป็นมะเร็งปากมดลูกระยะ 3 หรือ 4 พบว่ามีการกระจายเข้ากระเพาะปัสสาวะสูงกว่ากลุ่มที่เป็นระยะต้น นอกจากนี้ผลการตรวจปัสสาวะ ถ้ามี โปรตีน บิริรูบิน ไนไตรท์ เลือด หรือ เม็ดเลือดขาวในปัสสาวะ พบว่ามีความสัมพันธ์กับการกระจายเข้ากระเพาะปัสสาวะอย่างมีนัยสำคัญ โดยการวิเคราะห์จากหลายปัจจัยร่วมกัน พบว่าการมีโปรตีน หรือ ไนไตรท์ในปัสสาวะเป็นปัจจัยอิสระที่สัมพันธ์กับการกระจายเข้ากระเพาะปัสสาวะอย่างมีนัยสำคัญ ค่า OR 6.49 (95% CI 1.81-23.22) และ OR 3.77 (95% CI 1.17-12.07) ตามลำดับ และเมื่อนำปัจจัยทั้ง 2 ก่อนการส่องกล้องมาวิเคราะห์ร่วมกัน พบว่าการที่มี โปรตีน และไนไตรท์ในปัสสาวะ พบอุบัติการณ์การกระจายเข้ากระเพาะปัสสาวะร้อยละ 5 ถึง 20-30 ในมะเร็งปากมดลูกระยะ 3 และ ร้อยละ 30 ถึง 60-100 ในมะเร็งปากมดลูกระยะ 4*

สรุป: *การส่องกล้องกระเพาะปัสสาวะในผู้ป่วยมะเร็งปากมดลูก เพื่อประเมินการแพร่กระจายของโรค ควรเลือกทำในมะเร็งระยะหลัง 3 หรือ 4 โดยเฉพาะกลุ่มที่มีโปรตีนหรือไนไตรท์จากการตรวจปัสสาวะ*