The Impact of Regular Biopsy in the First Cystoscopic Follow-up and Other Predictors on the Recurrence of Superficial Bladder Tumors

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Background: To evaluate whether cystoscopic evaluations with bladder biopsy can serve as a significant predictor of superficial bladder tumor recurrence.

Methods: This study examined patients with superficial bladder cancer (Ta/T1). At the first three-month cystoscopic follow-up, subjects were divided into two groups: group 1 received cystoscopic examinations with transurethral bladder biopsy, and group 2 had a cystoscopic examination only. Patients without evidence of recurrence at the first three-month follow-up in these 2 groups (groups 1A and 2A) were compared with respect to recurrence rates and average recurrence time.

Results: One hundred and thirty patients were diagnosed with superficial bladder tumors. The mean follow-up time was 22.9 months. The two-year recurrence rates were 33.8% for Ta, 29.8% for T1, 30.4% for low-grade tumors, 31.9% intravesical for high-grade tumors, 26.4% in those treated with bacillus Calmette-Guerin therapy, 33.4% in those who had chemotherapy, 60% in the non-therapy group, 21.8% for single tumors and 47.9% for multiple tumors. Univariate and multivariate analysis revealed that tumor number and intravesical therapy were important predictive factors for tumor recurrence. The average recurrence times in groups 1A and 2A were 18.3 and 12.6 months, respectively, while the respective one-year/two-year recurrence rates were 2.4%/23.8% and 16.9%/22.1%. Univariate analysis showed no statistically significant differences between these two groups.

Conclusions: Our data support tumor number and intravesical therapy as important predictive factors for tumor recurrence. Cystoscopy combined with transurethral bladder biopsy mitigates tumor recurrence in the early years, but not in later years. Therefore, regular cystoscopic evaluation alone is sufficient for long-term patient surveillance.

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Key words: bladder neoplasm, bladder biopsy, superficial bladder tumor, re-biopsy

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Most bladder cancers first present as superficial tumors (Ta/T1), accounting for 70–80% of all bladder cancers.[1] Transurethral resection of bladder tumors (TUR-BT), with or without intravesical adjuvant therapy, is still the primary treatment for superficial bladder tumors. High recurrence rates and progression are the major problems; most recurrences manifest within three years. Re-staging TUR-BT has been suggested by several studies.[2,3] Herr showed that re-staging TUR-BT could increase the response to intravesical bacillus Calmette-Guerin (BCG) therapy in reducing tumor recurrence or progression.[4] In the literature, re-staging TUR-BT is typically done within two to six weeks of the first TUR-BT, but most urologists follow up patients at regular three-month intervals after completion of intravesical induction therapy. TUR-BT is repeated only when recurrence of a bladder tumor is identified. The effects of bladder biopsy in the first three-month cystocopic follow up are not well established. In the present study, we evaluated whether regular three-month cystoscopic evaluations with biopsy could be a predictive factor for superficial bladder tumor recurrence.

METHODS

This study analyzed patients with superficial bladder cancer (Ta/T1) who had been diagnosed at our hospital. All information was obtained via retrospective review of medical records. Briefly, all patients had already received their first complete TUR-BT. The operative procedure included resection of the bladder tumor, resection of any grossly suspected areas, and a deep biopsy of the tumor base for pathologic diagnosis, but random biopsy was not conducted during TUR-BT. Any patients with a pathological diagnosis of Ta or T1 received adjuvant intravesical therapy, according to the treatment guidelines of our hospital. Intravesical therapy with immunotherapy BCG, chemotherapy (mitomycin C [MMC], doxorubicin [DOX], or epirubicin [EPI]) was administered according to the pathological stage, tumor grading, tumor number, tumor size, the patient's general condition, the practice of the managing surgeon, and patient preference. The tumor number (single vs. multiple) and, in patients with a single tumors the size (< 1 cm/1–3 cm/ > 3 cm), were determined according to the records of the surgeon. A course of six weekly intravesical treatments was undertaken, after which patients received cystoscopic evaluations at three-month intervals for two years. If no tumor recurrence was noted during that time, cystoscopic evaluations were done to six-month intervals for an additional two years, followed by annual cystoscopic evaluations.

At the first cystoscopic follow-up after initial TUR-BT, patients were divided into two groups. Group 1 patients simultaneously received cystoscopies and transurethral bladder biopsies (where the biopsy site included the primary bladder tumor area, contra-lateral bladder wall, posterior wall, and trigone area). Group 1A patients were defined as those without tumor recurrence at the first three month follow-up, according to information in the pathological report. Group 2 patients received only cystoscopic evaluation. If a recurrent tumor was suspected, a TUR-BT was done at a later date. Group 2A patients were those defined as having no recurrence in the first three month follow-up, according to cystoscopic evaluation alone.

The end point of this study was tumor recurrence, which was defined as a cystoscopically identified and pathologically proven tumor. Recurrence data were calculated *via* Kaplan-Meier statistical analysis, and prognostic factors were evaluated via univariate analysis using the log rank test. Significant prognostic factors ($p < 0.1$) were then evaluated by multivariate analysis using the Cox proportional hazards regression method. Any $p < 0.05$ was considered statistically significant.

RESULTS

From October 2003 to September 2006, 130 patients with superficial bladder tumors (Ta/T1) were diagnosed in our hospital. The mean follow-up time was 22.9 months (3.0–41.5 months). Table 1 lists patient characteristics, tumor characteristics, and recurrence rates. Ninety-one of the 130 patients, were men. The mean age was 66.41 years (range, 25–93 years). Seventy patients (53.8%) received intravesical immunotherapy with BCG; 50 patients (38.5%) received intravesical chemotherapy with MMC, DOX, or EPI; and 10 patients (7.7%) did not receive intravesical therapy. The tumor stage was Ta in 54 patients (41.5%) and T1 in 76 patients (58.5%). Tumors Forty-six patients (35.4%) had low-grade

Table 1. Patient Characteristics and Recurrence Rates

Characteristics	Number (%)	Two-year recurrence rate (%)	*p* value
Total no.	130		
Mean age	66.41 years	(25–93 years)	
Mean follow-up time	22.9 months	(3–41.5 months)	
Gender			0.963
Male	91 (70)	32.6	
Female	39 (30)	29.1	
Tumor stage			0.502
Ta	54 (41.5)	33.8	
T1	76 (58.5)	29.8	
Pathological grade			0.706
Low (G1)	46 (35.4)	30.4	
High (G2 + G3)	84 (64.6)	31.9	
Intravesical infusion			0.027
BCG	70 (53.8)	26.4	
MMC / DOX / EPI	50 (38.5)	33.4	
None	10 (7.7)	60	
Tumor number			0.001
Single	81 (62.3)	21.8	
Multiple	49 (37.7)	47.9	
Tumor size (single)			0.763
< 1 cm	10 (12.3)	20	
1 cm–3 cm	57 (70.3)	24.4	
> 3 cm	14 (17.4)	15.4'	

Abbreviations: BCG: bacillus Calmette-Guerin; MMC: mitomycin C; DOX: doxorubicin; EPI: epirubicin.

and 84 (64.6%) had high-grade tumors. A single tumor was found in 81 patients (62.3%), with multiple tumors in 49 patients (37.7%). In single-tumor patients, the tumor size was less than 1 cm in 10 patients (12.3%), between 1 cm and 3 cm in 57 patients (70.3%), and larger than 3 cm in 14 patients (17.4%). There were 53 patients in group 1 and 77 patients in group?

A total of 42 of the 130 patients (32.3%) had tumor recurrence and the mean time to recurrence was 10.3 months (range 3–33 months). The two-year recurrence rate in men was 26.4% and in women, 29.1%. The two-year recurrence rate in Ta tumors was 33.8%, and in T1 tumors, 29.8%. The recurrence rate was 30.4% for low-grade and 31.9% for high-grade tumors. The two-year recurrence rate was 26.4% for the BCG immunotherapy group, 33.4% for the chemotherapy group, and 60% for the non-intravesical therapy group (Fig. 1). The two-year recurrence rate was 21.8% for patients with single tumors and 47.9% for patients with multiple tumors (Fig. 2). In the single-tumor group, the recurrence rates were 20% for the < 1 cm group, 24.4% for the 1–3 cm group, and 15.4% for the > 3 cm group. Univariate analysis revealed that tumor number (p = 0.001) and intravesical therapy (p = 0.027) were statistically significant prognostic factors. Multivariate analysis showed that tumor number (p = 0.002) and intravesical therapy (p = 0.042) were also important

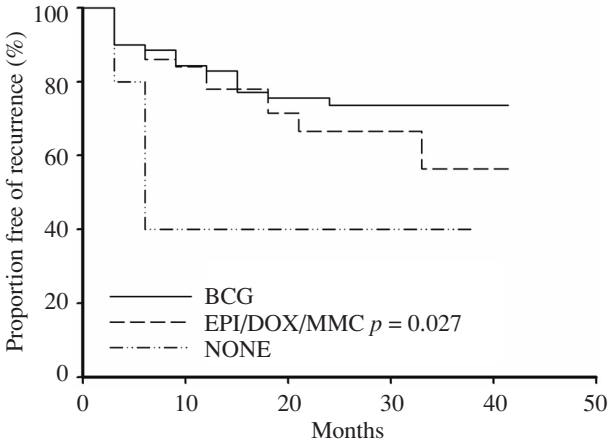

Fig. 1 Recurrence of superficial bladder tumors according to type of intravesical therapy.

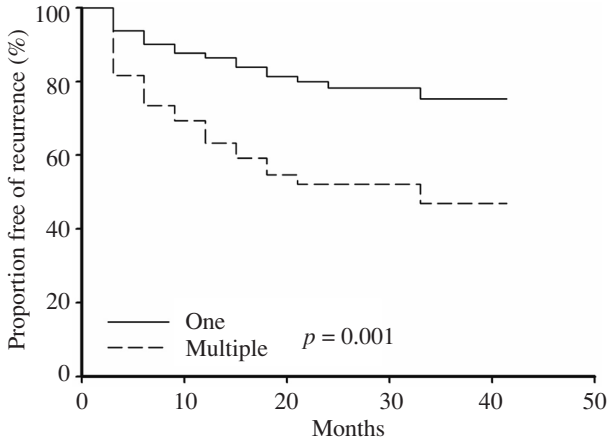

Fig. 2 Recurrence of superficial bladder tumors according to tumor number.

predictive factors for tumor recurrence.

Table 2 compares the patient characteristics in groups 1 (N = 53) and 2 (N = 77). Fourteen (26.4%) of the patients in group 1 had cystoscopically positive tumors in the first three-month follow-up. Biopsy testing was positive in 11 (20.7%) of the 53 patients; the false-positive rate for cystoscopy was 50% (7/14), and the false-negative rate was 10.2% (4/39). In group 2, 12 of the 77 patients were cystoscopically positive in the first three-month follow-up (15.6%), the false-positive rate was 58.3% (7/12).

Table 2. Comparison of Patient Characteristics in Groups 1 and 2

	Group 1*	Group 2†
Patient number	53	77
Gender		
Male	37	54
Female	16	23
Tumor number		
single	35	46
Multiple	18	31
Tumor size (single)		
< 1 cm	1	9
1 cm–3 cm	25	32
> 3 cm	9	5
Intravesical infusion		
BCG	25	45
MMC / DOX / EPI	25	25
None	3	7
Pathological stage		
Ta	25	29
T1	28	48
Pathological grade		
Low (G1)	18	28
High (G2+G3)	35	49
Cystoscopy positive	14	12
Pathology positive	7	5
Pathology negative	7	7
Cystoscopy negative	39	65
Pathology positive	4	No data
Pathology negative	35	No data

Abbreviations: BCG: bacillus Calmette-Guerin; MMC: mitomycin C; DOX: doxorubicin; EPI: epirubicin; TUR: transurethral resection; *: three-month cystoscopy + TUR-Biopsy; †: three-month cystoscopy only.

Patients in groups 1A and 2A were compared with respect to the time to later recurrence and one-year/two-year recurrence rates. Group 1A had a mean time to recurrence of 18.3 months, while that in group 2A was 12.6 months. The one-year/two-year recurrence rates in group 1A were 2.4%/23.8% and group 2A, 16.9%/22.1% (Fig. 3). However, univariate analysis with the log-rank test showed no statistically significant differences between the two groups ($p = 0.915$).

DISCUSSION

In Taiwan, bladder cancer is the eighth most prevalent malignancy among men, with an incidence rate of 12/100,000 and a five-year survival rate of 73%.[5] Early re-staging of TUR-BT has been suggested in many reports; however in clinical practice, most urologists perform regular follow-up cystoscopies at three-month intervals, and biopsies of bladder tumors only when a suspected recurrence has been noted on follow-up cystoscopy. Herr reported that repeated transurethral bladder biopsies can control non-invasive tumors and identify residual tumors, as the residual tumor rate can be as high as 76%.[6] Few published reports have mentioned follow-up bladder biopsy in clinical practice. This lack of supporting literature prompted us to initiate this

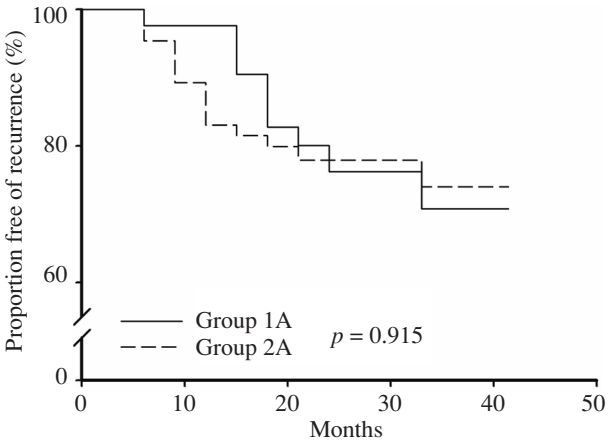

Fig. 3 Recurrence of bladder tumors in the groups 1A and 2A; Group 1A: Patients who had cystoscopic examination and transurethral bladder biopsy and were recurrence-free at 3 months; Group 2A: Patients who had cystoscopic examination only and were recurrence-free at 3 months.

study.

In this study the two-year recurrence rate with tumor staging among single-tumor patients was almost the opposite of that reported in most studies (recurrence rate: Ta/T1 = 33.8/29.8%; < 1 cm/1–3 cm/ > 3 cm = 20%/24.4%/15.4%).[7-9] Furthermore, our data revealed that tumor staging ($p = 0.502$) and tumor grading ($p = 0.607$) were not predictive factors for tumor recurrence. Yang et al. revealed that tumor grading, rather than tumor staging, is a prognostic factor for tumor recurrence.[9] Oge et al. also showed that the recurrence rate for grade 2 tumors was higher than that that for grade 1 (the three-, six-, nine-, and 12 -month recurrence rates in grade 2 were 8%, 8%, 6%, and 10.5%, respectively; in grade 1, 6%, 5%, 2.5%, and 7%, respectively).[8] On the other hand, Millan-Rodriguez et al. showed that Ta/T1 did not predict tumor recurrence,[10] and that grading was not a prognostic factor for tumor recurrence;[11] the latter finding is in comparable to findings in the current study.

There may be a number of reasons behind the relatively high recurrence rate of Ta, as well as the small tumor size in the single-tumor patients demonstrated in current study. First, Millan-Rodriguez et al. categorized bladder tumor patients into low-, intermediate-, and high-risk groups, by tumor stage and grade.[10] Intravesical therapy with BCG has been reported better than other modes of chemotherapy (i.e., MMC, DOX, and EPI).[12,13] Our data also revealed that patients who received BCG had a lower recurrence rate than other patients (BCG/MMC, DOX, EPI/none = 26.4%, 33.4%, and 60%, respectively). The 2008 National Comprehensive Cancer Network (NCCN) bladder cancer practice guidelines point out that in Ta/T1 high-grade or multiple tumors, BCG intravesical therapy is the preferable procedure; nonetheless, in our present data, 84 patients had high-grade tumors, but only 59.5% of them received BCG therapy. Fifty-two of 130 patients had a single high-grade tumor. BCG therapy was given to 40%, 66.7%, and 81.8% of those with tumors < 1 cm, 1–3 cm, and > 3 cm respectively. In Ta and T1 patients with single high-grade or multiple tumors, BCG therapy was given in 55.6% and 58.5%, respectively. The lack of regular intravesical therapy with BCG in multiple or high-grade bladder tumors as suggested by NCCN guidelines may be a major cause of reverse-trend data, such as that found in our study.

Second, inadequate resection of the primary tumor may also be an important reason for this reverse-trend data. In our hospital, the TUR-BT procedure is carried out not only by the uro-oncology surgeons, but also by other specialists; inadequate resections of tumor (e.g., incomplete removal, not deep enough into muscle, etc.) may influence the pathological diagnosis. Incomplete resection of bladder tumors was reported by several studies; in one study, residual tumor material could be found in 76% of cases during a second TUR-BT.[6] Incomplete tumor removal may cause early tumor recurrence and progression.

Third, there was a limited number of patients with tumors larger than 3 cm (N = 14) in this study, and this small sample size may have skewed our data. Our hospital has updated its bladder tumor treatment guidelines and all urologists are now in compliance. In addition to excision of the bladder tumor and grossly suspected bladder mucosa, random biopsy from the normal mucosa must be done in a first TUR-BT. This may change our recurrence rate data in the future.

Our study revealed that tumor number and intravesical therapy are the most important prognostic factors for tumor recurrence. The findings of Millan-Rodriguez et al. are consistent with those of the current study.[11] Kiemeney et al. analyzed 1,674 cases and found that tumor stage, tumor extent, and multicentricity were prognostic factors for recurrence.[14] Mulders et al. showed that tumor location and multiplicity were prognostic factors.[15] Pycha pointed out that generalized genetic instability of the bladder urothelium may be due to problems stemming from the multi-focal character of bladder tumors.[16] Zurkirchen et al. reported that for patients with multiple bladder tumors, one TUR-BT may not be sufficient in completely removing a bladder tumor, even when the procedure is done by an experienced urologist.[17]

In our study, the 2-year recurrence rate among multiple-tumor patients was twice as high as that for single-tumor patients (47.9% vs. 21.8%). For multiple-tumor cases the one-year/two-year recurrence rates for group 1A were better than those for group 2A (7.7%/31.6% and 29.6%/38.5%, respectively). Regular cystoscopy with bladder biopsy may be more important in patients with multiple tumors.

Several reports have shown that intravesical therapy decreases the recurrence rate of bladder tumors;[11,18] and our data also showed that intravesical therapy with BCG or other drugs promises better recurrence control than regimens lacking therapy ($p = 0.027$). Intravesical therapy, in the form of BCG or other modes, is quite important in the prevention of tumor recurrence.

In patients with regular three-month follow-ups, cystoscopy with or without concurrent bladder biopsy is another important issue. Herr revealed that re-staging TUR-BT improved the response rate to BCG therapy;[4] Brauers et al. also found that it offers the possibility for bladder preservation.[3] Dalbagni et al. reported that 13% of T1 patients receiving a cystectomy after TUR-BT had a pathological stage greater than T1.[19] Inaccurate diagnoses of bladder tumors have also been mentioned in the literature.[20] Paulson revealed that 35% of patients with T1 were understaged.[20] On the other hand, with most cases of bladder cancer, the patient's age, medical condition, anesthesia risk, personal comfort, cost effect, and efficacy should be considered. In clinical practice, most patients hesitate to accept TUR-BT re-staging within a short time; follow-ups at regular three-month intervals are more suitable for our patients.

On the first follow-up cystoscopic examination, our patients who had a bladder biopsy and did not have tumor recurrence in the pathological report experienced longer times to recurrence than those with only a negative cystoscopic result; the recurrence time ranged from 12.6 to 18.3 months. The recurrence rates, 2.4% in group 1A and 16.9% in group 2A ($p = 0.022$), were also significantly different in the first year. The longer time to recurrence in group 1A than 2A may have occurred because patients with positive pathology who were going to receive a 2nd TUR-BT were excluded. The time to recurrence of the other patients should be longer. Unfortunately, the two-year recurrence rates were no different, with recurrence rates of 23.8% in group 1A and 22.1% in group 2A. The log-rank test also revealed no statistical significance between the two groups ($p = 0.915$).

Regular follow-up cystoscopy, without biopsy, may be done on an out-patient basis, under local anesthesia. Cystoscopic evaluation with bladder biopsy, however, should be performed in an operating room under general or spinal anesthesia, as there is more pain with this combination of treatments than with cystoscopy alone. Highshaw et al. revealed that a three- or six-month bladder biopsy is not necessary when cystoscopic results are negative;[21] our data supports the assertion. Our study revealed that tumor number and intravesical therapy are the important predictive factors for tumor recurrence. Cystoscopy, combined with transurethral bladder biopsy during the first three-month follow-up mitigates tumor recurrence in the early years, but not in later years. Thus, regular cystoscopic evaluation alone is enough for long-term surveillance of patients.

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膀胱鏡合併切片檢查與其他預測因子對表淺性膀胱腫瘤復發的影響

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背 景： 評估是否定期 3 個月膀胱鏡檢查合併膀胱切片，可做爲表淺性膀胱腫瘤復發之參考因子。

方 法： 此研究以本院診斷爲表淺性膀胱腫瘤爲對象。所有病患一開始均接受完整內視鏡腫瘤刮除手術。第一次定期膀胱鏡追蹤時，將病患分成兩組。一組接受膀胱鏡檢查合併膀胱切片，另一組則單純接受膀胱鏡檢查。針對兩組皆無腫瘤復發之病患，加以比較其一年與兩年腫瘤復發率與平均復發時間。

結 果： 總共 130 位病患診斷爲表淺性膀胱腫瘤，平均追蹤 22.9 個月。在兩年復發率方面 Ta/T1 = 33.8% / 29.8%；Low grade / high grade = 30.4% / 31.9%；膀胱內灌藥：BCG/化學藥物 / 無治療= 26.4 % / 33.4% / 60%；膀胱腫瘤數目：單一 / 多處= 21.8% /47.9%。單變項分析和多變項分析顯示，膀胱腫瘤數目與膀胱內灌藥有明顯統計意義。第一次定期膀胱鏡追蹤無復發之病患，合併膀胱切片平均復發時間爲 18.3 個月，一年 / 兩年復發率爲 2.4%/23.8%。單純膀胱鏡檢查之病患，平均復發時間爲 12.6 個月，一年 / 兩年復發率爲 16.9%/22.1%。但統計學上，兩組並無明顯差異。

結 論： 我們資料顯示，膀胱腫瘤數目與膀胱內灌藥，在腫瘤復發預測上有明顯統計意義。第一次定期膀胱鏡檢查合併膀胱切片，可延長病患早期腫瘤復發時間。但就長期追蹤而言，膀胱鏡檢查即已足夠。

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關鍵詞：膀胱腫瘤，膀胱切片，表淺性膀胱腫瘤，再切片

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