Does Adequate Bladder Cuff Excision Impact Outcomes in Patients Undergoing Nephroureterectomy for Upper Tract Urothelial Carcinoma

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Background: Nephroureterectomy with bladder cuff excision has been the gold standard surgical treatment for upper tract urothelial carcinoma. In this study, we determined the independent prognostic factors for upper tract urothelial carcinoma.

Methods: The records of 285 consecutive patients undergoing nephroureterectomy with bladder cuff excision at our institution between 2003 and 2007 were reviewed. Kaplan-Meier survival curves were used to determine the 5-year cancer-specific survival rates for all patient groups. Cox proportional hazard regression was performed to determine the factors that had an independent impact on the survival of patients with upper tract urothelial carcinoma.

Results: A total of 192 patients matching the inclusion criteria were enrolled in our study. The mean follow-up time was 43.81 months. We found that the female gender, a lower ureter free of invasion, and an adequate bladder cuff excision were independent factors for a better tumor recurrence-free survival rate. The pathology stage and recurrence (none, intravesical or extravesical) were independent factors for the overall survival rate. A non-adequate ureterectomy including the bladder cuff was associated with a high body mass index (BMI) and the infiltrating tumor pattern of urothelial carcinoma.

Conclusion: Nnephroureterectomy together with adequate bladder cuff excision plays an extremely important role in the surgical treatment of upper urinary tract urothelial carcinoma. Patients with incomplete resections of the bladder cuff are at increased risk of tumor recurrence.
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Key words: urinary bladder, urinary tract, urothelium, neoplasm recurrence

Urothelial carcinoma of the upper urinary tract is relatively rare. It occurs in about 5-7% of patients with renal tumors and about 5% of patients with urothelial tumors.[1] However, an unusually high incidence of upper urinary tract urothelial carcinoma has been reported in Taiwan,[2] and the local recurrence rates are high. In the literature, about 20-70% of the patients who undergo nephroureterectomy with bladder cuff excision have tumor recurrence in a remaining ureteral stump or in the bladder.[3-6] In

recent decades, this operation has been the gold standard treatment for such malignancies. The whole ureter, including the intramural portion and the orifice, should be completely excised.[7] Technical difficulties may be encountered when performing this operation. In obese patients, the bladder is deep in the pelvic cavity, and the surgical field is limited. In addition, if the patient has a history of intrapelvic surgery or if the tumor has invaded the lower ureter, inflammatory and adhesion changes surrounding the ureter and bladder increase the difficulty of performing a bladder cuff excision. Although complete bladder cuff excision has been recommended by most authors, few studies have reviewed postoperative cystoscopies to examine whether bladder cuffs were completely excised. In addition, few recent studies have focused on the impact of adequate bladder cuff excision on tumor recurrence-free survival and overall survival. The aim of this study was to analyze patients with upper tract urothelial carcinoma who underwent nephroureterectomy with bladder cuff excision by an extravesical method. We tried to identify the independent factors affecting the tumor recurrence-free survival rates and overall survival rates. We also tried to determine whether an adequate bladder cuff excision is one of these factors.

METHODS

The records of 285 consecutive patients who underwent nephroureterectomy with bladder cuff excision at Chang Gung Memorial Hospital between 2003 and 2007 were reviewed. All operations were performed by well-experienced urologic surgeons at our institution. The included patients had no history of either bladder cancer or any other malignancy before surgery. The operative method was nephroureterectomy with bladder cuff excision using an extravesical method, and the pathology reports all indicated the presence of urothelial carcinoma. The patients underwent a cystoscopy 3 months after the nephroureterectomy, and findings at the ipsilateral orifice were recorded. A cystoscopy was performed every 3 months during the first 2 years after surgery, followed by half-yearly examinations. As soon as tumor recurrence was suspected in a clinical evaluation, computed tomography (CT) or magnetic resonance imaging (MRI) was performed. Patients were excluded if they had any of the following; organ transplantation with immunosuppressant therapy, contralateral malignancies requiring bilateral operations, concomitant bladder tumor requiring a transurethral resection (TURBT), a partial cystectomy or a cystectomy either performed alone or with nephroureterectomy, and lack of a bladder cuff excision, for any reason. In addition, patients who were lost to follow-up or had missing cystoscopy data were also excluded from this study.

A total of 192 patients matched our criteria. Their medical histories, physical examinations, lab data, preoperative and postoperative image studies, including ultrasonography, intravenous pyelography, cystoscopy, retrograde pyelography, CT, and MRI, surgical findings, and final pathology reports, were recorded in detail. Adequate bladder cuff excision was defined as scarring on the previous orifice site of the bladder cuff excision as shown on cystoscopy. The tumors were staged according to the American Joint Committee on Cancer criteria stage system, 6th edition, and the tumor grading was performed according to the World Health Organization /International Society of Urological grading system, 1998. The Cox proportional-hazards regression model was applied to identify independent factors affecting the tumor recurrence-free survival rate and the overall survival rate of the patients. Finally the survival curves were described in Kaplan-Meier plots.

RESULTS

There were 79 men and 113 women enrolled in our study, with a mean age of 69.78 (43-89) years. The mean follow-up time was 43.81 (3.77-84.77) months. Thirty-seven (19.27%) patients had a history of either an intrapelvic or intra-abdominal operation. Eighty-two (42.71%) patients presented with stage I disease, and 41 (21.35%), 54 (28.13%), and 15 (7.81%) patients presented with stage II, III, and IV disease, respectively. The infiltrative type of tumor morphology was seen in 116 (60.42%) cases, and the papillary type in 76 (39.58%). One hundred and seventy-nine (93.23%) cases were high-grade urothelial carcinoma, while the rest were low-grade (6.77%). One hundred and fifty-five (80.73%) patients had solitary tumors, 31 (16.15%) had 2 tumors, and 6 (1.12%) had 3 or more tumors. Fifty-two patients had tumors in the left kidney, 12 in the left kidney

and left ureter, and 37 in the left ureter. Forty-five patients had tumors in the right kidney. 17 in the right kidney and left ureter, and 29 in the right ureter. A total of 95 patients had upper urothelial carcinoma involving the ureter, of whom 21 (10.94%) also had lower ureter involvement.

One hundred (52.08%) patients underwent a midline laparotomy, 37 (19.27%) a flank and Gibson incision, 11 (5.73%) an extended Gibson incision, and 44 (22.92%) a hand-assisted laparoscopic operation. In the 3 -month postoperative cystoscopy, 114 (59.37%) patients had scarring on the previous orifice site, which, by our definition, meant that there was adequate intramural resection of the ureter. In contrast, 78 (40.63%) patients had an intact orifice on the site of the bladder cuff excision, implying inadequate excision of the intramural ureter. Eighty-nine (46.35%) patients had tumor recurrence in our study, with a mean of time-to-recurrence of 10.2 (1-69.8) months. The first tumor recurrence in 57 (64.04%) of these patients was an intravesical tumor, which could be cauterized by TURBT, while an extravesical leison was the first recurrent tumor in 32 (35.96%) patients. The most common site of extravesical recurrence was the lung (12 patients), followed by the paravesical area (5 patients), ipsilateral renal fossa (5 patients), and liver (3 patients).

During the mean 43.81 month follow-up, the tumor recurrence rates (intravesical or extravesical) were 36.59%, 58.54%, 81.48%, and 80.00%, for stage I to stage IV, respectively. In addition, the intravesical recurrence rates for stage I to stage IV were 31.71%, 48.78%, 51.58%, and 20.00%, respectively. In other words, the intravesical recurrence rate for stage I was the lowest of all, followed by stage II. The tumor recurrence rates for stage III and IV were similar, however, these were mostly extravesical recurrences in stage IV patients (Stage IV: 60.00% vs stage III: 29.63%). The Cox proportional-hazards regression model was applied to identify possible independent factors that affected the tumor recurrence-free survival rates after the operation, such as gender, tumor grade (high/low), tumor morphology (infiltrating/papillary), pathology stage (I-IV), number of tumors, tumor location (renal pelvic/ureter), lower ureter involvement and adequacy of bladder cuff excision. As shown in Table 1, gender, adequacy of bladder cuff excision, and lower ureter involvement were the independent factors affecting tumor

Table 1. Analyses of Factors of Possible Predictive Value in the Tumor Recurrence-free Survival Rate

	Multivariate analysis	
	HR (95% CI)	p value
Female gender	0.498 (0.326-0.761)	0.001*
Inadequate bladder cuff excision	3.536 (2.245-5.568)	< 0.001*
Lower ureter involvement	1.951 (1.123-3.389)	0.018*
Pathology stage	1.125 (0.909-1.392)	0.279

*: $p < 0.05$.

recurrence. Fig. 1 reveals the relationship between these factors and the tumor recurrence-free survival rates. Female patients, those with an adequate bladder cuff excision and those with lower ureters free of invasion had better tumor recurrence-free survival rates than the other patients. Since adequate bladder cuff excision is an important factor contributing to tumor recurrence, and most recurrences were in the bladder, we further analyzed the different stages to see whether an adequate bladder cuff excision affected tumor intravesical recurrence. As shown in Fig. 2, we found that for stage I, II and III, all patients who had complete removal of the bladder cuff had better intravesical tumor recurrence free survival rates. However, because of the small case number for stage IV, this figure was not statistically significant. We further investigated the location of bladder tumor recurrence, and found that the adequate excision group had 18 recurrences in the bladder, with a total of 24 tumors. Five of the recurrent tumors were near the ipsilateral trigone (27.78%). Two of the remaining recurrent tumors were in the base, 4 in the bladder neck, 4 in the dome, 6 in the ipsilateral lateral wall, 1 in the contralateral lateral wall, and 2 in the posterior wall. For the inadequate excision group, there were 39 cases of recurrence in the bladder, with a total of 49 tumors. Among these, 21 recurrent tumors were near the ipsilateral trigone (53.85%), 4 were in the bladder neck, 7 in the dome, 7 in the ipsilateral lateral wall, 2 in the contralateral lateral wall, 9 in the posterioral wall, and 2 in the contralateral trigone. There was a higher percentage of tumor recurrence in the ipsilateral trigone in those with an inadequate bladder cuff excision compared with the adequate excision group (53.85% vs 27.78%, p = 0.0891). This was close to being statistically significant.
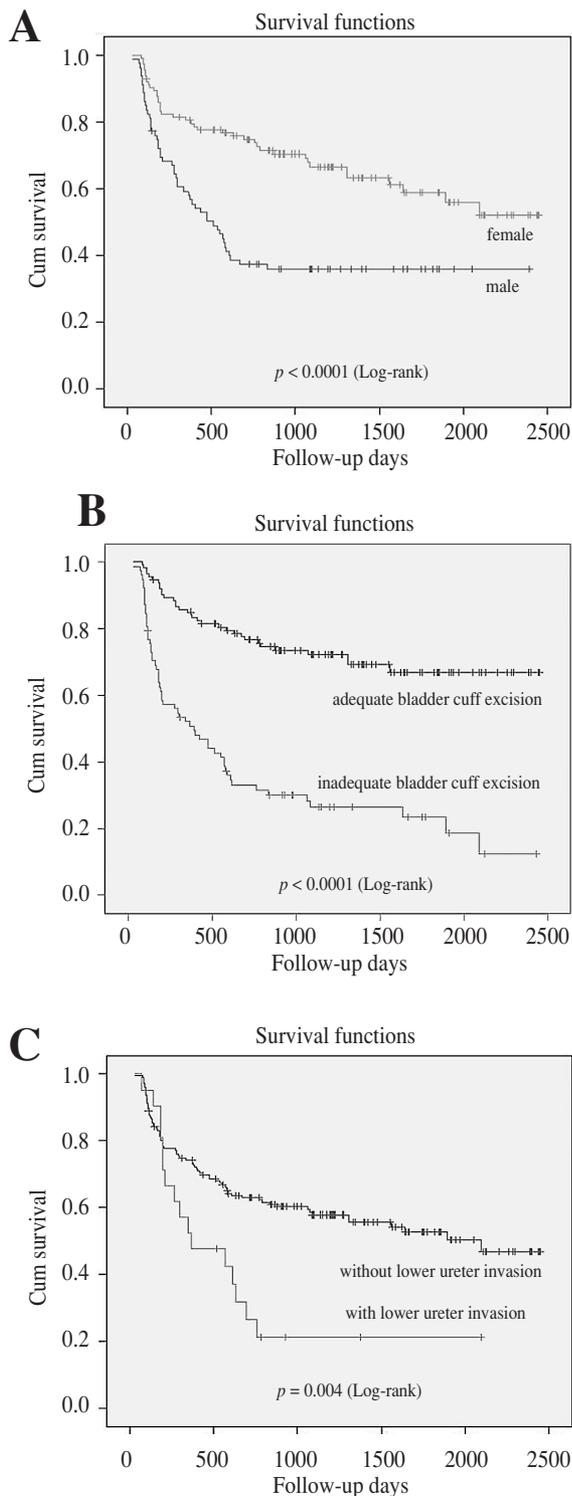
Fig. 1 Actuarial freedom from disease recurrence by gender (A), adequate bladder cuff excision (B), and location (C).

Independent factors that affected the overall survival rates were disease having reached the pathologic stage and recurrence (none, intravescial, extravesical), as shown in Table 2. The survival curves are shown in Fig. 3. In contrast, gender, adequacy of bladder cuff excision, lower ureter involvement, tumor morphology, number of tumors, tumor location, and tumor grade were not independent factors affecting the overall survival rates in our study.

Table 3 reveals the relationship between adequate bladder cuff excision and the patient characteristics. We used multivariate analysis to analyze possible factors affecting adequate bladder cuff excision. As shown in Table 4, we found that patients presenting at an early pathologic stage, as well as those with a lower BMI, were more likely to have complete bladder cuff excisions. On the contrary, factors such as the tumor type (papillary or infiltrative), lower ureter involvement, tumor grade, and use of laparoscopic surgery showed no direct relation with bladder cuff excision.

DISCUSSION

Unlike other urological malignancies, the characteristics of upper tract urothelial carcinoma are unique, because its cells can spread via the urine and implant in raw urothelium. The standard surgical treatment for the disease therefore consists of 2 different procedures, a nephrectomy and removal of the entire ureter including the bladder cuff. Conservative surgical treatment without radical resection of the whole upper urinary tract leads to high tumor recurrence rates of about 70-90%. This approach has been suggested only in selected cases, such as patients with solitary low-stage lesions or impaired renal function.[8,9] In a study in the Taiwanese population by Tan et al., the recurrence rate after total nephroureterectomy with bladder cuff excision was about 13%, which was lower than rates reported after incomplete ureterectomy.[10] Other reports revealed tumor recurrence in the bladder in about 15-50% of patients who underwent nephroureterectomy,[11-13] which emphasizes the importance of regular cystoscopic follow-ups after the operation. However, most studies compared patients with and without bladder cuff excision, rather than those with and without adequate excisions. The authors did not reexamine any of the complete ureteral resections by
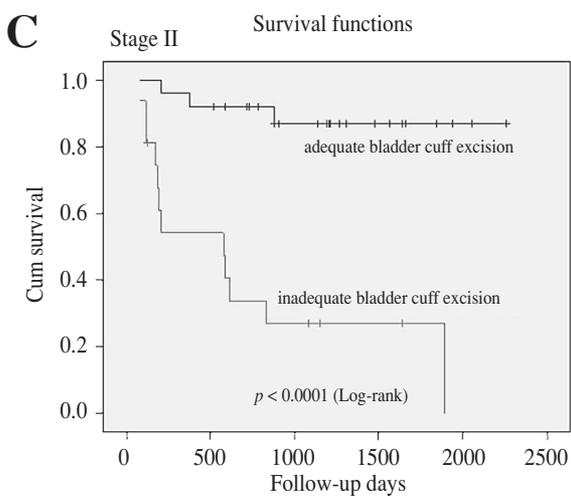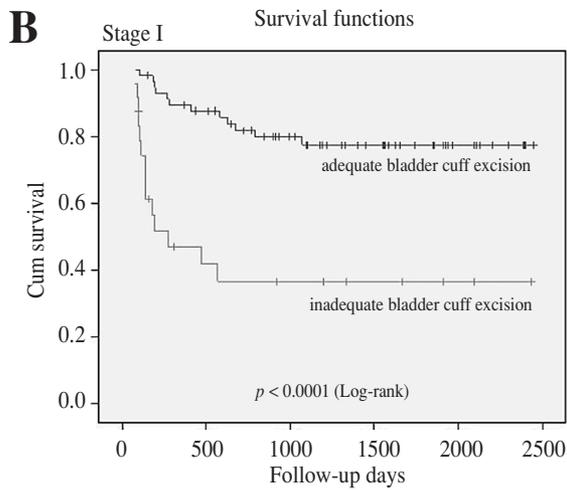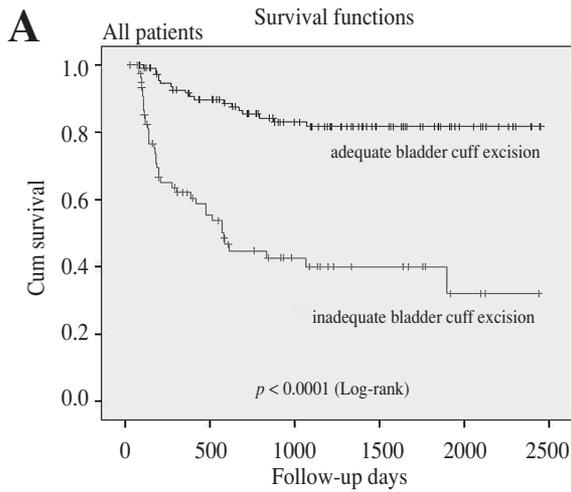
Table 2. Analysis of Factors of Possible Predictive Value for the Overall Survival Rate

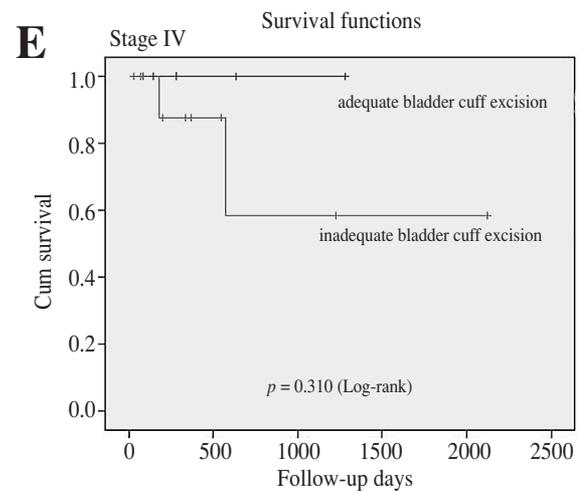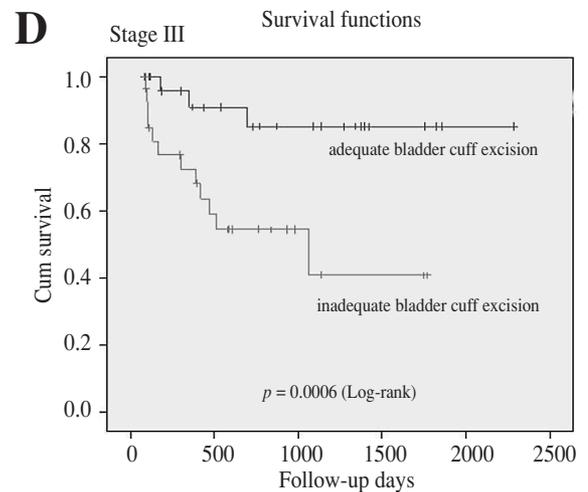|	Multivariate analysis	
	HR (95% CI)	*p* value
Female gender	0.986 (0.484-2.010)	0.970
Pathology stage	1.636 (1.113-2.403)	0.012*
Tumor number	1.268 (0.686-2.345)	0.449
Ureter tumor	1.679 (0.795-3.546)	0.174
Recurrence condition	2.828 (1.812-4.414)	< 0.001*

*: $p < 0.05$.

Fig. 2 Intravesical recurrence free survival curves for all patients (A), and those with stage I (B), stage II(C), stage III (D), and stage IV disease (E) who had adequate and inadequate bladder cuff excisions.
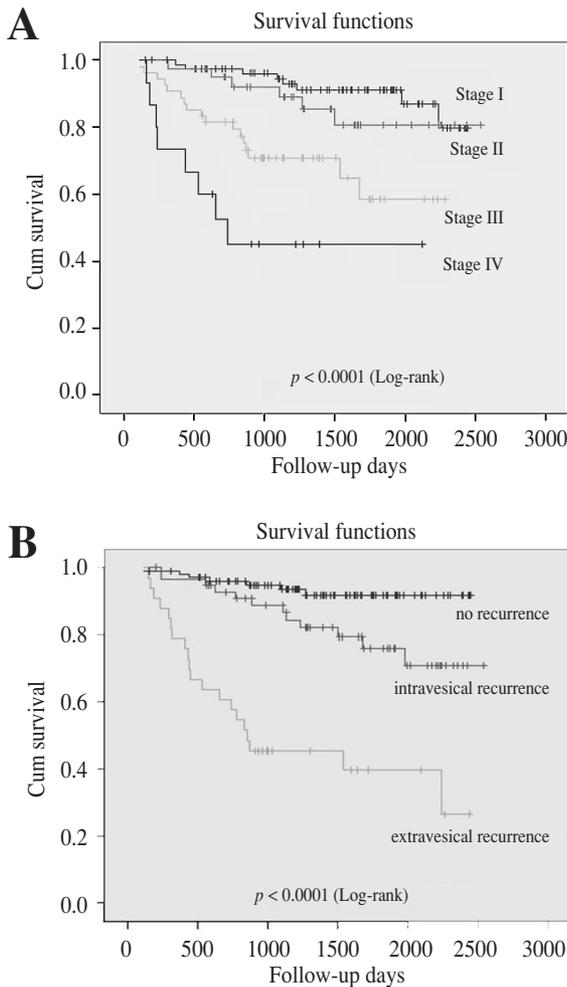
A

B

Fig. 3 Overall survival curves for pathologic stages (A) and recurrence (B).

Table 3. Relationships between Patient Characteristics and Bladder Cuff Excision

Characteristic	Adequate excision N (%)	Inadequate excision N (%)
BMI	22.95 (16.22-38.16)	26.32 (15.01-39.64)
History of abdominal or pelvic operation		
No (%)	92 (59.4%)	63 (40.6%)
Yes (%)	22 (59.5%)	15 (40.5%)
Tumor Involving lower ureter		
Yes (%)	11 (52.4%)	10 (47.6%)
No (%)	103 (60.2%)	68 (39.8%)
Tumor number		
1	93 (60%)	62 (40%)
2	19 (61.3%)	12 (38.7%)
≧ 3	2 (33.3%)	4 (66.7%)
Pathology stage		
I	58 (70.7%)	24 (29.3%)
II	25 (61.0%)	16 (39.0%)
III	26 (48.1%)	28 (51.9%)
IV	5 (33.3%)	10 (66.7%)
Tumor morphology		
Infiltrating	61 (52.6%)	55 (47.4%)
Papillary	53 (69.7%)	23 (30.3%)
Tumor grade		
High	105 (58.7%)	74 (41.3%)
Low	9 (69.2%)	4 (30.8%)
Operative method		
Midline laparotomy	57 (57.0%)	43 (43.0%)
Flank + Gibson	23 (62.2%)	14 (37.8%)
Extended Gibson	9 (81.8%)	2 (18.2%)
Hand-assisted laparoscopic	25 (56.8%)	19 (43.2%)
Total	114 (59.4%)	78 (40.6%)

cystoscopy. Inadequate resection of the intramural part of the ureter often occurs when a urologic surgeon believes that the bladder cuff needs to be excised completely, especially when the procedure is performed by an extravesical method. We were interested in knowing whether inadequate resection affects the tumor recurrence rate and the overall survival rate, as well as whether bladder cuff excision is more difficult to perfom in some types of patients. To the best of our knowledge, these issues have not been widely discussed in the literature.

A strict definition of adequate bladder cuff excision–scarring on the site of the previous orifice as shown by cystoscopy–was applied in our study. As shown in Table 1, adequate bladder cuff excision was a strong independent factor affecting tumor recurrence. Fig. 1B also shows that tumor recurrence-free survival rates were significantly different between patients with adequate and inadequate excisions. This result implies that a urologic surgeon should excise the bladder cuff as completely as possible when performing a nephroureterectomy. In our study, 43.65% of patients had tumor recurrence. The mean time to recurrence was 10.2 months. These data were

Table 4. Multivariate Analysis of Possible Predictive Values for Adequate Bladder Cuff Excision

	Multivariate analysis	
	HR (95% CI)	p value
Infiltrative type	0.759 (0.607-1.949)	0.522
Lower ureter invasion	0.735 (0.336-1.686)	0.491
High grade tumor	0.971 (0.901-1.046)	0.447
Lower BMI (< mean value)	2.261 (1.567-3.263)	< 0.001*
Stage I or II	1.420 (1.113-1.811)	0.002*
Laparoscopic surgery	0.900 (0.534-1.518)	0.411

*: $p < 0.05$.

similar to the average in other reports. Among the patients with tumor recurrence, 64.04% presented with an intravesical tumor as the first recurrent lesion. A similar result was presented by Abe et al. in 2009. In that study, 113 (40%) patients developed bladder tumors at a median interval of 9 (2–105) months after nephroureterectomy.[14] These results indicate that tumor recurrence in the bladder after nephroureterectomy is of a refractory nature, and that life-long, regular cystoscopic follow- ups are crucial. Another independent factor for high tumor recurrence was lower ureter involvement. This might be due to the fact that the shorter the distance between the primary tumor and the bladder mucosa, the easier malignant cells can spread via the urine and implant themselves in the bladder urothelium when the lower ureter is manipulated during the operation. Our study also showed that women had a lower tumor recurrence rate. However, there might be some bias in this finding, because urothelial carcinoma is by nature a male-predominant malignant disease.[15,16]

It is interesting that the independent factors that affected tumor recurrence did not significantly affect the overall survival rates, as shown in Table 2. Only the pathologic stage and recurrence (none, intravesical, extracesical) significantly affected the overall survival rates in our study. The 5-year-survival rates of the patients with stages I, II, III, and IV were 91.2%, 82.4%, 63.5%, and 42.7%, respectively. As shown in Fig. 3B, patients without tumor recurrence had the best overall survival rates, while those with the first recurrence as an extravesical lesion had the worst. Nevertheless, although our data revealed that

patients with tumors involving the ureter had overall survival rates similar to patients with renal involvement only, whether tumor location affects the overall survival rate has been a matter of debate. Some studies reported significantly higher cancer-specific mortality rates in patients with primary ureteral urothelial carcinoma.[17-19] Conversely, others indicated that when renal pelvic and ureteral tumors were matched according to stage, there was no significant difference in the prognosis.[20]

A complete distal ureterectomy with bladder cuff excision can be performed by extravesical and intravesical methods, and by a transurethral incision. A recent study revealed no differences in recurrence-free and cancer-specific survival among these 3 methods.[21] The extravesical method is performed most often at our institution. The need for a cystostomy is avoided with this approach. When performing this procedure, the ureter is tented up and the bladder mucosa is divided between clamps. The defect in the bladder wall is closed in layers with absorbable sutures. At our institution, transurethral endoscopic techniques for bladder cuff excision, such as the pluck technique, intussusception technique, and transvesical laparoscopic ligation-detachment technique, are not commonly applied. Although they provide assurance of complete orifice occlusion, exposure of nonurothelial surfaces, which might create a predisposition to local recurrence, is a concern.[22-24] In addition, patients undergoing this procedure have to be placed in a lithotomy position after the nephroureterectomy is carried out, which increases the operating time and technical difficulties.

Our study focused on the patients who underwent bladder cuff excision by the extravesical method, with a total of 114 (59.4%) patients receiving adequate excision by our definition. Approximately 40% of all of our cases had an inadequate removal of the orifice because we adopted a strict standard of a scarred region where the orifice was originally found as shown on cystoscopy. After bladder cuff excision, it is possible to find parts of the orifice on post-surgery follow-up cystoscopy even when an intramural ureterectomy has been carefully performed. Whether the remaining orifice was responsible for giving rise to subsequent tumor recurrence was the main focus of our interest. To the best of our knowledge, this topic has not been investigated in literature to date. Furthermore, from our

statistical analysis, even a small amount of remaining intramural tissue increases the likelihood of tumor recurrence in the bladder. Therefore, apart from the follow-up cystoscopy which checks for any recurrences in the bladder, it is also important to observe whether an orifice exists. This finding once again stresses the importance of bladder cuff excision, and the significance of carrying out this procedure in a meticulous manner.

In our study, the BMI was a strong independent factor of adequate excision. The mean BMI of the patients who had adequate excisions was 22.95, which was significantly lower than those with inadequate excisions (mean BMI = 26.32). This finding implies that entire removal of the ureter is difficult to perform perfectly on obese patients, since the bladder is deep in the pelvic cavity and the surgical field is limited. Another factor that affected a complete bladder cuff excision was the pathologic stage ($p = 0.002$). The laparoscopic approach did not affect the adequate excision rate ($p = 0.411$). Before analyzing our data, we hypothesized that lower ureter involvement would decrease the adequate excision rate, because inflammatory and adhesion changes surrounding the ureter and the bladder increase the difficulty of bladder cuff excision. However, our results did not seem to correspond with our experience in practice. This might be because there there were only 21 patients with lower ureter involvement compared to 171 without, which might have caused a bias in the statistics.

Although this study has offered convincing results, there were still a number of weaknesses. First, the statistical procedures were retrospective; therefore, we were unable to randomly assign patients to designated doctors for the surgical procedure. We believe that surgeons play an important role in performing a complete and adequate removal of the bladder cuff. Because we were unable to include this issue in our statistical analysis, it was possible for bias to occur. Second, it was found that patients who had an inadequate bladder cuff excision had a higher rate of tumor recurrence in the bladder. Nevertheless, close to half of this population (46.15%) did not have tumor recurrence near the ipsilateral trigone. As a result, we were unable to prove that these recurrences were a direct result of inadequate bladder cuff excision. Last, we adopted an "all-or-none" strategy when considering tumor recurrence. However, some patients only had one recurrence in the bladder whereas others had multiple recurrences. We were unable to further investigate the clinical differences between these two groups of patients. Therefore, it is necessary to carry out more prospective studies focusing on the above-mentioned points to better understand upper tract urothelial carcinoma.

Conclusion

The present study showed that nephroureterectomy together with adequate bladder cuff excision plays an extremely important role in the surgical treatment of upper urinary tract urothelial carcinoma. An adequate bladder cuff excision was identified as one of the independent factors affecting the tumor recurrence-free survival rate. A surgeon should excise the bladder cuff as completely as possible, and life-long regular cystoscopic follow-ups are necessary. Meanwhile, bladder cuff excision with the extravesical method is not suggested for obese patients, because it is technically difficult to remove the entire intramural ureter of these patients.

Acknowledgements

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腎臟切除手術併輸尿管全切除包含袖口切除在輸尿管惡性腫瘤之預後因子之評估

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背 景： 上泌尿道癌以腎臟和輸尿管包含袖口全切除是標準手術方法，本研究是探討上泌尿道癌之輸尿管包含袖口全切除手術是否是重要的手術後之預後因子。

方 法： 這項回顧性研究是收集 2003 年至 2007 年間有 285 位上泌尿道癌病人接受腎臟和輸尿管包含袖口全切除後，平均追蹤 43 個月，利用 Cox proportional hazard regression 及Kaplan-Meier 存活率的統計方法來探討腎臟和輸尿管包含袖口全切除後，那些因子是手術預後因子。

結 果： 總共有 192 位病人符合本研究納入標準，病人接受腎臟和輸尿管包含袖口全切除手術後，我們發現女性病患、下段輸尿管未遭腫瘤侵犯、以及完整的膀胱袖口切除，其腫瘤較不易復發。病理期別與初次復發位置則是影響整體存活率的獨立因子。而身體質量指數較高、浸潤性腫瘤的患者，較不易達到完整的膀胱袖口切除。

結 論： 完整的膀胱袖口切除在手術治療上泌尿道癌非常重要。若膀胱袖口切除不完全，會增加腫瘤復發的機率。

(長庚醫誌 2011;34:496-505)

關鍵詞：膀胱，泌尿道，泌尿上皮，腫瘤復發