

Oncological Outcomes of Radical Cystectomy for Transitional Cell Carcinoma of Bladder

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Objective: To investigate the oncological outcome of radical cystectomy for muscle invasive bladder (MIBC) on cancer-specific survival.

Material and Method: A consecutive series of patients undergoing radical cystectomy from 2004 to 2012 were recorded. The prognostic significance of several clinicopathologic factors in these patients were analyzed. The endpoint of oncological outcome was cancer-specific survival (CSS). The effect of clinical variables on CSS were statistically analysed by a log-rank test or Cox regression with hazard ratios. All analyses were performed using a 0.05 level of significance.

Results: One hundred eleven patients were analyzed. The average patient age when cystectomy was carried out was 65 (35 - 84) years. The 5-year cancer-specific survival rate was 36% for all 111 patients. The 5-year cancer-specific survival rates for patients with clinical T1, T2, T3 and T4 were 89%, 32%, 30% and 11.6%, respectively. Positive lymph nodes were found in 26 patients (23.4%) who had a 5-year cancer-specific survival 12.9%. Of several factors examined, univariate analysis identified tumor stage, nodal status, metastasis, margin positive and lymphovascular invasion (LVI) as significant predictors of OS, of which tumor stage and nodal status appeared to be independently related to overall survival on multivariate analysis.

Conclusion: Radical cystectomy is a standard treatment for muscle invasive bladder cancer. Oncologic outcomes of radical cystectomy is generally favorable, however, surgery alone had no more potential to prolong survival of patients with invasive cancer, multimodal treatment approaches might need.

Keywords: Transitional cell carcinoma of bladder, radical cystectomy, survival, MIBC

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In Thailand, incidence of bladder cancer is 4.4/100,000 in male and 1.2/100,000 in female⁽¹⁾. About 25% of patients newly diagnosed with bladder cancer have muscle-invasive bladder cancer (MIBC)⁽²⁾. Patients with MIBC have a poorer prognosis than those with non-MIBC. Radical cystectomy with pelvic lymph nodes dissection is a standard treatment of muscle invasive bladder cancer, including non-muscle invasive bladder cancer that cannot be treated by bladder

preservation therapy⁽³⁾ and has been shown to be effective for MIBC^(4,5). The pathologic stage of the primary tumor (T stage) and regional lymph node status (N stage) have been shown to be the most accurate predictors of disease recurrence after radical cystectomy^(7,8). Although oncological outcomes and prognosis after radical cystectomy for bladder cancer have been reported^(6,7) but less is known about the outcomes in Thai patients. The authors therefore evaluated and assessed the outcome of a consecutive series of patients who underwent radical cystectomy MIBC which focusing on cancer-specific survival, the association between clinicopathologic features and clinical outcomes in Songklanagarind Hospital.

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Material and Method

We retrospectively reviewed all the medical records of 111 patients underwent radical cystectomy for transitional cell carcinoma of bladder from February 2004 to October 2012 at Songklanagarind Hospital. All parameters were analyzed included age and gender. Pathologic staging (TNM) was classified following the American Joint Committee on Cancer (AJCC) 2010. All procedures were performed under general anesthesia and patients were monitored after surgery. Radical cystectomy in male patient was performed by en bloc removal of bladder with surrounding perivesical soft tissue, seminal vesicles and prostate gland. In female, the uterus, both ovaries and anterior vaginal wall were removed. Simultaneous bilateral pelvic lymph nodes dissection was routinely done. Nephroureterectomy was concomitantly performed in patient with synchronous upper urinary tract tumor. Urinary diversion was done with two main techniques: ileal conduit and ilealneobladder, depended on surgeon and patient preference. Ureteral stents were placed by using feeding tube and removed postoperatively. The survival was recorded at our tumor registry unit. The study was approved by the Institutional Review Board (IRB) of Songklanagarind Hospital Ethic Committee. All clinicopathologic, treatment and response data were extracted from a retrospective review of hospital charts and medical records.

Pathologic evaluation

All surgical specimens were processed according to standard pathological procedures. Tumors were graded according to the 2004 WHO grading system⁽⁹⁾, and all tumors restaged according to the 2010 American Joint Committee on Cancer tumor node metastasis (TNM) staging system⁽¹⁰⁾. Positive surgical margin of both urethra or ureter were considered as margin positive in this analysis⁽¹¹⁾. Lymphovascular invasion was defined as the unequivocal presence of tumor cells in an endothelium-lined space but not in the underlying muscular walls⁽¹²⁾.

Follow-up

After radical cystectomy, patients were generally followed up every 3 months during the first year, every 6 months during years 2 - 6, and annually thereafter. Follow-up consisted of history taking, physical

examination, blood laboratory investigations, and urine analysis. Imaging included chest radiography, computed tomography of the abdomen and pelvis, all performed at 6 and 12 months postoperatively and annually thereafter. Death from cancer was documented and used to calculate cancer-specific survival.

Statistical analysis

Quantitative data are expressed as mean and percentage. Cancer-specific survival (CSS) was measured from the date of initiation of treatment to the date of death from bladder cancer. CSS curves were calculated by the Kaplan-Meier method and compared using the log-rank test. A Cox proportional hazard regression model was used to estimate the prognostic significance of each variable. All statistical tests were 2-tailed, with $p < 0.05$ considered significant. Correlations between outcomes and variables are expressed as hazards ratio (HR) with 95% confidence intervals (CIs). All statistical analyses were performed using R program version 2.9.0.

Results

Patient characteristics

Patient's demographic data and clinicopathologic outcomes were summarized in Table 1. Total patients in the present study was 111. Mean age was 65.14 years. Of these, 101 (91%) were male and 10 (9%) were female, 12 (10.8%) underwent ilealneobladder and 99 (89.2%) underwent ileal conduit as urinary diversions. Pathological staging confirmed that 85 patients (76.6%) had node-negative disease and 26 (23.4%) had lymph node metastases. A total of 46 (44.4%) patients had organ-confined primary tumors (pT2 or less), 13 (11.7%) had lymphovascular invasion (LVI), and 98 (88.3%) had negative surgical margins. Postoperative adjuvant chemotherapy was administered to 7 patients (6.3%).

Cancer-specific survival

The median and mean followup were 30 and 24 months. The median cancer-specific survival rate was 36% for all 111 patients as shown in Figure 1A. The 5-year cancer-specific survival rates for patients with clinical T1, T2, T3 and T4 were 89%, 32%, 30% and 11.6%, respectively.

Of several factors examined, univariate analysis identified tumor stage, nodal status, metastases, positive margin and lymphovascular invasion (LVI) were significant predictors of OS. Furthermore, tumor stage and nodal status appeared to be independently related to poor overall survival on multivariate analysis.

Complications

Complications graded by the Clavien classification system were 55% in grade II (urinary tract infection, blood transfusion, ileus, lymphatic leakage, delirium, infectious peritonitis, vesico-urethral anastomotic leakage, uretero-pouch anastomotic leakage, neobladder leakage) and for grade IIIa (rupture of incision required 2-stage stage suture) and IIIb (Intraoperative damage of external iliac vessels) complications requiring surgical intervention were 8% and 2% respectively.

Discussion

Muscle invasive bladder cancer (MIBC) is generally an aggressive disease also requiring aggressive therapy, with fewer than 15% of untreated patients surviving to 24 months after diagnosis⁽¹³⁾. The goals of treatment for any invasive bladder cancer include improvement of overall survival rates, prevention of local recurrences in the form of distant metastases, and preservation of a higher quality of life.

Contemporary series demonstrated that radical cystectomy alone can provide a 5-year overall survival rate ranging between 48% and 58%⁽¹⁴⁻¹⁸⁾. The authors underline the oncological outcomes of radical cystectomy in The present study was generally favorable with 36% 5-year cancer-specific survival rate. This figure may equivalent or lower than some previous reported. It might be from higher proportion of non organ-confined tumor ($\geq T3$) of population (58.5%). However, focusing on the survival according to T stage, the 5-year CSS for patients with pathologic T1, T2, T3 and T4 were 89%, 32%, 30% and 11.6%, respectively, which comparable to previous study which 5-year crude survival rates for T2, T3 and T4 were 33%, 15% and 14%, respectively⁽¹⁹⁾. The figure from our study may inferior to some reports which 5-year CSS were 60-70% in T2 and 40-50% in T3 and 20% in N1 stage which might be from heterogeneity of disease and various treatment. On multivariate analysis, the present study found that pathologic stage is an important survival determinant in patients undergoing radical cystectomy for bladder cancer. In addition, certain pathologic subgroups stratify patients into different prognostic categories. The 46 patients (41.4%) with pathologically organ-confined bladder tumors had excellent survival outcomes, whereas the patients with extravesical invasion or lymph node metastasis had a poor prognosis. The reported incidence of regional

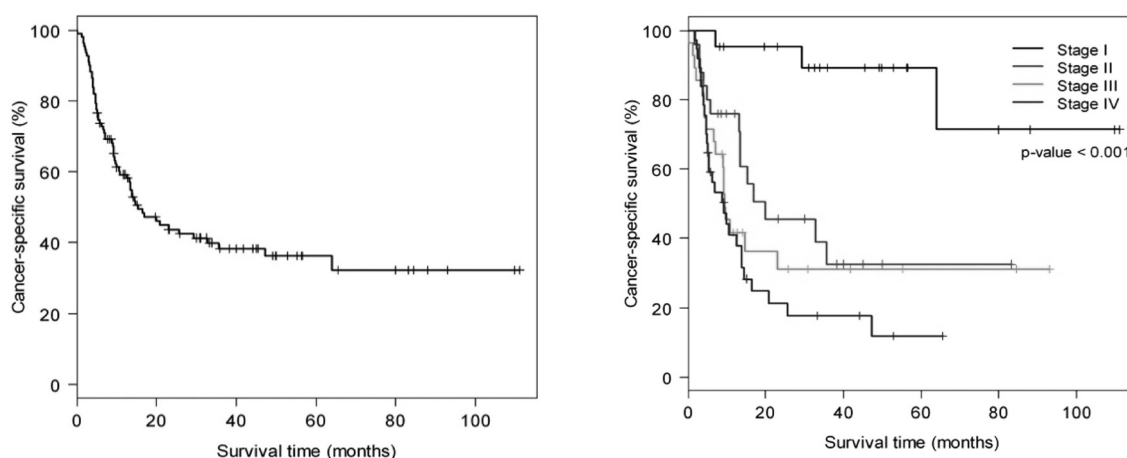


Fig. 1 (A) Kaplan-Meier survival curves showed cancer specific survival post radical cystectomy, (B) Cancer-specific survival of 111 MIBC patients who underwent radical cystectomy according to T stage.

Table 1. Patient's demographic data

parameters	number	percent (%)
Age, (year), Mean (SD), Range (year)	65.14, 66, (35-84)	
Gender		
Male	101	91
Female	10	9
ECOG (performance status)		
0	8	7.2
1	103	92.8
Length of stay, mean (day)	14	
Time to cystectomy from diagnosis		
<= 3 months	57	51.4
> 3 months	54	48.6
Type of diversion		
Neobladder	12	10.8
Ileal conduit	99	89.2
Treatment		
Surgery alone	79	71.2
Adjuvant CMT	7	6.3
Adjuvant RT	25	22.5
Tumor grading		
High grade	101	91
Low grade	10	9
Tumor staging (T-stage)		
T1	21	18.9
T2	25	22.5
T3	28	25.2
T4	37	33.3
Nodal status (N-stage)		
N0	85	76.6
N1	26	23.4
Metastasis (M-stage)		
M0	108	97.3
M1	3	2.7
Pathologic		
Transitional cell carcinoma	99	89.2
TCC with squamous differentiation	12	10.8
Surgical margin		
Negative	98	88.3
Positive	13	11.7
Ureteric margin		
Negative	108	97.3
Positive	3	2.7
Lymphovascular invasion (LVI)		
Absent	62	55.9
Present	49	44.1

Table 2. Univariate and multivariate analysis of association between parameters and cancer-specific survival

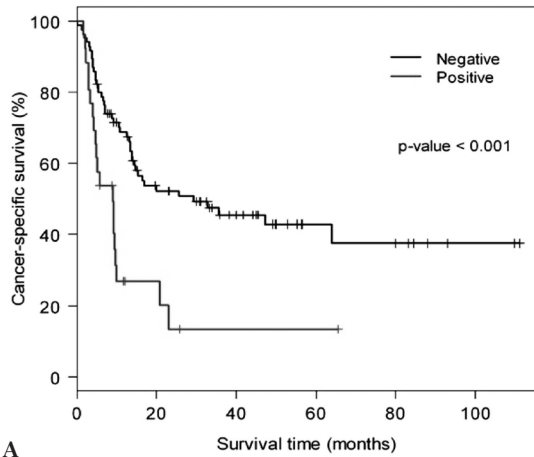
parameter	Univariate analysis		Multivariate analysis	
	HR (95% CI)	<i>p</i> -value	HR (95% CI)	<i>p</i> -value
Age : > 60 or ≤ 60 year	1.69 (0.96-2.98)	0.07	1.63	0.12
ECOG : 1 vs 0	1.91 (0.6-6.08)	0.276	-	-
Time to cystectomy				
>3 month vs ≤ 3 month	0.88 (0.54-1.44)	0.613	-	-
T-stage				
1		0.001**		
2	6.1 (1.74-21.28)	0.005	5.61 (1.53-19.65)	0.007**
3	8.8 (2.58-30.07)	0.001	6.73 (1.76-23.87)	0.003**
4	11.97 (3.61-39.66)	0.001	5.95 (1.45-21.53)	0.006**
N-stage				
positive or negative	2.62 (1.52-4.51)	0.001**	1.95 (0.86-3.93)	0.041**
M-stage				
positive or negative	4.03 (1.24-13.08)	0.02**	1.84 (0.38-5.17)	0.61
LVI				
present or absent	2.81 (1.68-4.68)	0.001**	1.11 (0.53-2.32)	0.77
Surgical margin				
positive vs negative	2.89 (1.53-5.46)	0.001**	2.19 (0.97-4.98)	0.06
Diversion type				
ileal conduit vs neobladder	3.73 (1.17-11.93)	0.026**	2.48 (0.76-8.09)	0.131
Grading:				
low grade vs high grade	0.47 (0.17-1.31)	0.149	-	-
Adjuvant treatment				
No		0.002**	-	-
CMT	0	0.997	-	-
RT	1.75 (1.02,2.99)	0.042	-	-

** 95% confidential interval

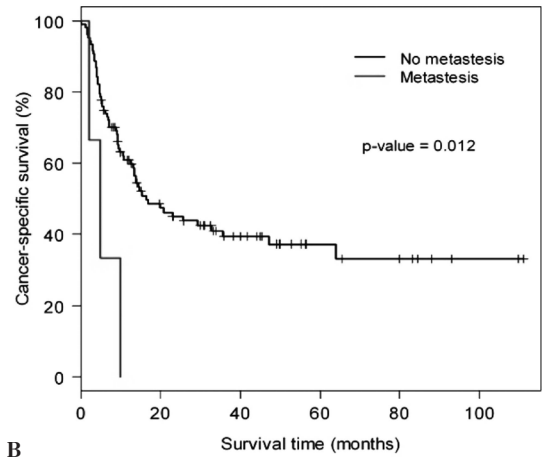
lymph node involvement varies between 18% and 24%^(6,15,17) and the author reported 23.4% of patients had lymph node metastasis. Other studies reported 5-year overall survival following radical cystectomy for node positive cases regardless of stage ranged between 21% and 31%^(6,15,17,18). The result of our study showed 5 yr CSS rates of 12.9% which lymph node metastasis compared to 42.6% without lymph node metastasis. On multivariate analysis examined node positivity has been an independent poor prognosis on cancer-specific survival. Moreover, we found adjuvant chemotherapy (Gemcitabine plus cisplatin) administration in 7 of 111 patient (6.3%) examined had better survival compared those with radiotherapy or surgery alone on univariate analysis significantly ($p = 0.012$). Reported from meta-

analysis suggests a survival benefit to adjuvant therapy for pathologic T3, T4 or N+ disease at cystectomy⁽²⁰⁾, promising treatment from chemotherapy, we also treated these patients with adjuvant chemotherapy for improving overall survival.

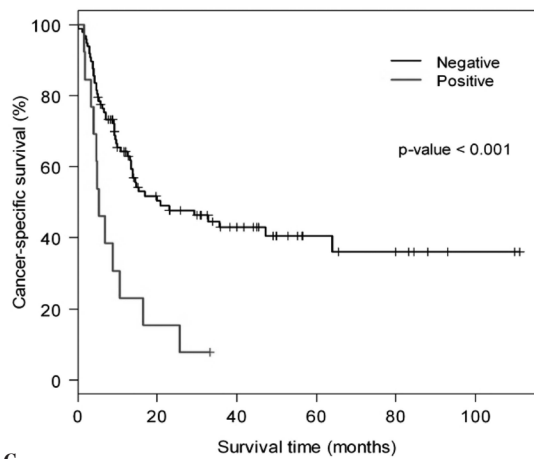
After radical cystectomy, patients with extra-vesical tumor extension or lymph node-positive disease were at increased risk for recurrence and may therefore benefit from adjuvant chemotherapy. Standard chemotherapy usually comprises of gemcitabine and cisplatin. Response rates of up to 35% and a median survival of 6 months have been reported. Urinary diversion after radical cystectomy is either continent or non-continent. Most of patient have a non-continent ileal conduit formed where the ureters are anastomosed



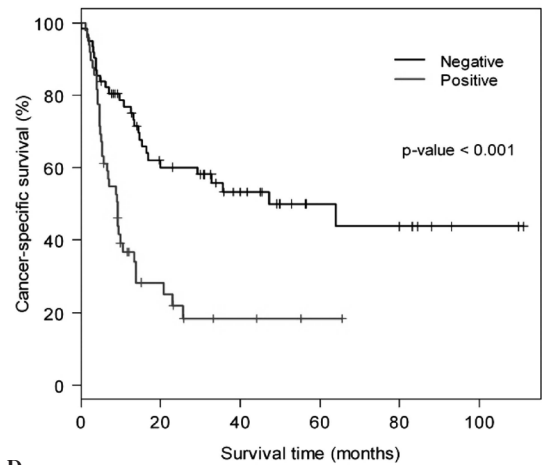
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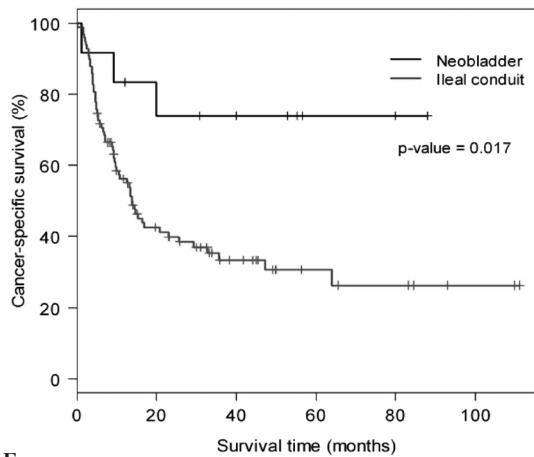
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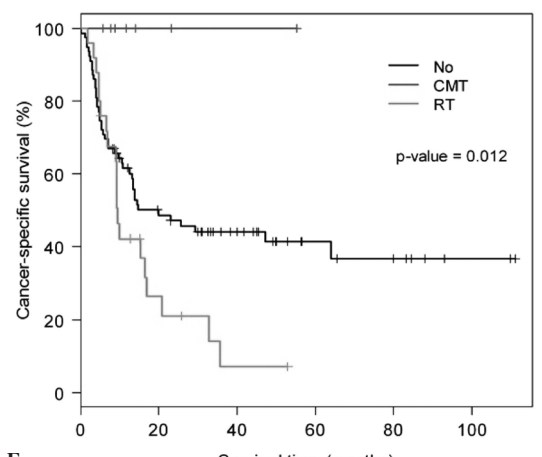
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Fig. 2 (A-F) Cancer-specific survival of 111 patients with transitional carcinoma who undergone radical cystectomy according to (A)node metastasis, (B) distant metastasis(M stage), (C) Surgical margin status, (D) lymphovascular invasion (LVI), (E) diversion type, (F) adjuvant treatment.

to an isolated short length of ileum that is fashioned into a stoma on the anterior abdominal wall were 99 of 111 (90%) due to advanced disease (extravesical invasion and LN metastasis) which need further adjuvant treatment. We observe in our hospital that, patients may recover faster compared to neobladder diversion which is technically complex and requires longer operative time and also need longer time for voiding adaptation, gain weight until full recovery. However, current guidelines recommend orthotopic bladder substitute (OBS) in patients without contraindications and without tumors in the urethra or at the level of urethral dissection⁽²¹⁾. The option of lower urinary tract reconstruction to the urethra has also been shown to decrease physician reluctance and increase patient acceptance of earlier cystectomy for bladder cancer, when the disease may be more curable⁽²²⁾ and can improve quality of life in some patients (avoiding a stoma). Although there are no randomized clinical trials comparing the orthotopic neobladder with the ileal conduit, results of several retrospective analyses have not shown substantial differences in overall surgical complication rates. Time from diagnosis to cystectomy also plays important impact on survival. The previous study showed that a delay of more than 12 weeks between diagnosis and radical cystectomy for TCC of the urinary bladder significantly compromises patient survival. This adverse impact affects both disease-specific and overall survival and is exacerbated by increasing time from diagnosis to cystectomy and identified a 12-week cutoff as conferring an increased risk of pathologic upstaging and mortality⁽²³⁾. However, the present study showed the time from TURBT to radical cystectomy at a 3-month cutoff has no significant association with prognosis on univariate analysis ($p = 0.613$).

Conclusion

Radical cystectomy provides good survival results in patients with bladder cancer. The pathologic features, T-stage and N-stage were identified as independent predictors of cancer-specific survival in Thai patient with MIBC which pathologic T-stage \geq T3 or node metastasis showed significantly associated with poorer prognosis. Whether greater use of proven effective systemic therapy or multimodality approaches will improve outcome in the future needs to be evaluated.

What is already known on this topic?

About 25% of patients newly diagnosed with bladder cancer have muscle-invasive bladder cancer (MIBC)⁽²⁾. Patients with MIBC have a poorer prognosis than those with non-MIBC. Radical cystectomy with pelvic lymph nodes dissection is still a standard treatment of muscle invasive bladder cancer and in non-muscle invasive bladder cancer that cannot be treated by bladder preservation therapy⁽³⁾ and has been shown to be effective against MIBC^(4,5). The pathologic stage of the primary tumor (T stage) and regional lymph node status (N stage) have been shown to be the most accurate predictors of disease recurrence after radical cystectomy^(7,8). Oncological outcomes and prognosis after radical cystectomy for bladder cancer have been reported^(6,7).

What is this study adds?

Radical cystectomy for bladder cancer is still a standard treatment for muscle invasive bladder cancer long-term survival. Our study of radical cystectomy focus on Thai patient in Songklanagarind Hospital for 10 year period provided an overall survival equivalent to studies reported previously, but surgery alone had no more potential to prolong survival of patients with invasive cancer. In conclusion, radical cystectomy provides good survival results in patients with bladder cancer. The pathologic features, T-stage and N-stage were identified as independent predictor of cancer-specific survival in Thai men with MIBC which pathologic T-stage \geq T3 or node metastases showed significantly associated with poorer prognosis and whether greater use of proven effective systemic therapy or multimodality approaches will improve outcome in the future needs to be evaluated.

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Potential conflicts of interest

None.

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ผลการรักษาผู้ป่วยมะเร็งกระเพาะปัสสาวะชนิด *transitional cell* ด้วยวิธีการผ่าตัดกระเพาะปัสสาวะร่วมกับต่อมน้ำเหลือง

รณัญญ์ เพชรานนท์, ชุศักดิ์ ปรพัฒนานนท์, มณฑิรา ตัณฑานุช, วาทีต กาญจนวนิชกุล

จุดประสงค์: ศึกษาแบบย้อนหลังเพื่อประเมินผลการรักษาผู้ป่วยมะเร็งกระเพาะปัสสาวะชนิด *transitional cell* ด้วยวิธีการผ่าตัดกระเพาะปัสสาวะร่วมกับต่อมน้ำเหลือง

วัสดุและวิธีการ: ผู้ป่วยมะเร็งกระเพาะปัสสาวะชนิด *transitional cell* ด้วยวิธีการผ่าตัดกระเพาะปัสสาวะร่วมกับต่อมน้ำเหลือง จำนวน 111 รายในช่วงระหว่างปีพ.ศ. 2547 จนถึง พ.ศ. 2555 และวิเคราะห์ปัจจัยที่ส่งผลกระทบต่อการอยู่รอดของผู้ป่วย *cancer-specific survival* โดยใช้การเครื่องมือวิเคราะห์ *log-rank* หรือ *Cox regression* และ *hazard ratios* โดยทุกการวิเคราะห์จะใช้นัยสำคัญที่ 0.05

ผลการศึกษา: จากผู้ป่วย 111 ราย พบว่าอายุเฉลี่ย 65 ปีอัตราการรอดชีวิตจากมะเร็งกระเพาะปัสสาวะที่ 5 ปีอยู่ที่ร้อยละ 36 อัตราการรอดชีวิตจากมะเร็งกระเพาะปัสสาวะที่ 5 ปี แยกตามระยะของก้อนเนื้อ T1, T2, T3 และ T4 อยู่ที่ร้อยละ 89, 32, 30 และ 11.6 ตามลำดับ มีการแพร่กระจายไปต่อมน้ำเหลือง 26 ราย คิดเป็นร้อยละ 23.4 อัตราการรอดชีวิตจากมะเร็งกระเพาะปัสสาวะที่ 5 ปีอยู่ที่ร้อยละ 12.9 จากการศึกษาปัจจัยที่ส่งผลกระทบต่ออัตราการอยู่รอด พบว่าระยะของก้อนเนื้อออก การแพร่กระจายไปยังต่อมน้ำเหลือง การแพร่กระจายไปที่อวัยวะอื่น การเหลือเนื้ออกที่บริเวณผ่าตัด รวมถึงลักษณะพยาธิสภาพที่มีมะเร็งอยู่ในต่อมน้ำเหลืองและท่อเลือด (LVI) เป็นปัจจัยที่ส่งผลกระทบต่ออัตราการอยู่รอดอย่างมีนัยสำคัญทางสถิติ แต่เมื่อวิเคราะห์ตัวแปรหลายปัจจัยร่วมพบว่าเฉพาะระยะของก้อนเนื้ออย่างมีนัยสำคัญ

สรุป: การรักษาผู้ป่วยมะเร็งกระเพาะปัสสาวะด้วยการผ่าตัด ยังคงเป็นการรักษาที่ได้มาตรฐาน มีผลการรักษาที่ดี ช่วยเพิ่มอัตราการอยู่รอดของผู้ป่วย อย่างไรก็ตามอาจพิจารณาให้ยาเคมีบำบัดเพื่อเพิ่มอัตราการอยู่รอดให้ผู้ป่วยมะเร็งกระเพาะปัสสาวะ
