The Outcomes and Prognostic Factors of Patients with Soft-Tissue Sarcoma

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The present study evaluates the outcomes and prognostic factors in patients with soft-tissue sarcomas of the extremities, trunk, head and neck region. A retrospective study of 104 patients who underwent treatment was conducted on 48 males and 56 females with a mean age of 44.5 years (range, 10-85 years). Seventy-eight patients had high-grade sarcomas and most tumors (89.5 percent) were located at the extremities. One hundred patients were treated by surgery and 51 patients were treated by both surgery and radiation therapy. With the median follow-up time of 24.5 months, local recurrence developed in 26 patients (25 percent) and distant metastasis developed in 29 patients (27.9 percent). The actuarial overall 3-year disease-specific survival rate were 74.2 percent. Multivariate statistical analysis revealed that positive surgical margin and occurrence of distant metastasis were significant predictors for overall survival. Positive surgical margin was the only factor that increased the risk of local recurrence and older age (≥ 60 years) was only the factor that increased the risk of distant metastasis. The results reaffirm the importance of the surgical margin where uncontrolled local disease affects the risk of local failure and disease-specific survival. Occurrence of distant metastasis is associated with older age (≥ 60 years) and decreases disease-specific survival of the patients.

Keywords: *Soft-tissue sarcoma, Outcomes, Prognostic factors*

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Soft-tissue sarcomas are a relatively rare neoplasm and constitute less than 1 percent of all cancers[1-2]. Based on data from the American Cancer Society, it was estimated that 8,100 new cases of soft-tissue sarcoma developed during 2000 in the United States[2]. The management of these tumors is difficult necessitating the use of a combined multidisciplinary approach. The prognosis of patients with soft-tissue sarcoma depends on many factors including grade, location, size, lymph node and organ metastasis. At the authors' institution, multidisciplinary care was first introduced in patients with osteosarcoma in 1984 and was then provided for all patients with malignant musculoskeletal tumors[3]. Many studies have documented the prognostic factors and the results of treatment in soft-tissue sarcomas[4-9]. The present study was conducted with patients diagnosed as having soft-tissue sarcoma and treated at the authors' institute. The present study demonstrated the prognostic factors of the treatment results in terms of the oncologic outcomes and patterns of disease relapse, with the aim of improving the understanding and management of this disease.

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Material and Method

The medical records of all patients with soft-tissue sarcoma of the extremities, head, neck and trunk regions (excluding retroperitoneum) treated at the Department of Orthopaedic Surgery, Faculty of Medicine Siriraj Hospital between January 1992 and

December 2002 were retrospectively reviewed. One hundred and twenty-nine patients were identified. Twenty-five patients did not have enough data or were lost during follow-up, leaving 104 with complete clinical, operative and pathological data.

All patients were treated with a combination of surgery and radiation therapy unless it was felt that satisfactory margins had been obtained by surgery alone. The main objective of the treatment was to achieve clear surgical margins while maximizing the patients' function. Surgical margins were classified as not free margin when tumor cells were seen at the margin of the surgical specimen, and as closed margin when tumor cells were involved within 1 centimeter from the dyed surface of the surgical specimen and free margin if tumor cells were identified more than 1 centimeter from the dyed surface of the surgical specimen. Grading of soft-tissue sarcoma used the histopathologic subtype as the definition of grade for most sarcoma[10]. For analysis in the present study, intermediate grade tumors that seemed to be aggressive were classified as being in the high-grade group, and those that seemed to be less aggressive were classified as being in the low-grade group.

Information was collected for each patient and then clinical and pathologic variables were correlated with survival end points. Patient variables included patient age and sex at the time of diagnosis. Tumor variables included tumor size, anatomic site, surgical margins, tumor grade, type of presentation, occurrence of local recurrence and distant metastasis after initial treatment. Because treatment was not prospectively randomized, the inclusion of treatment variables in any of the analyses would confound the effects of other factors. Therefore, while the authors reported the treatment data, the authors chose not to include them in any of the analyses.

Three-year disease-specific and disease-free survivals were modeled with the Kaplan-Meier method[11]. Death confirmed to be caused by the disease was treated as an end point for disease-specific survival; other deaths were treated as censored observations. Disease-free survival was segregated into local recurrence-free and distant metastasis-free survival. Survival curves were compared using log-rank testing for univariate analysis and Cox model stepwise regression for multivariate influence. To arrive at a parsimonious multivariated model, covariates were selected only if they contributed significantly to the fit of the model. A p-value of less than 0.05 was considered statistical significant.

Results

All data from the 104 patients forming the basis of this review were analyzed as of November 2003. The mean and median follow-up time was 32.9 months (range 1-135) and 24.5 months, respectively. The mean age was 44.5 years (range 10-85). There were 48 male and 56 female (ratio 1:1.7). Seventy-four tumors were located in the lower extremities (71.2 percent), 19 patients were in the upper extremities (18.3 percent) and 11 were in head, neck and trunk regions (10.6 percent). Ninety-eight tumors (94.2 percent) were 5 centimeters or more in size and 6 (5.8 percent) were less than 5 centimeters in size. Seventy-eight tumors (75 percent) were high-grade and 26 tumors (25 percent) were low-grade. The margins of 64 tumors (61.5 percent) were free from tumor cells, 20 were closed margin (19.2 percent), 17 were not free (16.3 percent) and the other three tumors were only biopsied. Sixty-three patients (60.6 percent) received primary treatment at this hospital, 26 (25 percent) presented with recurrent disease and 15 patients (14.4 percent) had tumor removal at another hospital and came for adjuvant treatment such as radiation therapy, chemotherapy or further investigations. A summary of the characteristic of patients and tumors is shown in Table 1. Of the overall group, 4 patients (3.8 percent) were inoperable cases due to the size and difficult location of the tumor and they were all treated palliatively. One hundred patients (96.2 percent) were treated with surgery, 51 patients (49 percent) were treated with adjuvant radiation therapy and 23 patients (22.1 percent) were treated with adjuvant chemotherapy.

The data from 104 cases were analyzed on univariate and multivariate basis with respect to disease-specific survival, local disease-free survival and distant metastasis-free survival for variables.

Disease-Specific Survival - All Patients

At the time of analysis, 80 patients (76.9 percent) were alive of whom 55 patients (52.9 percent) had been continuously disease-free, 4 patients (3.8 percent) had no evidence of disease and 21 patients (20.2 percent) were alive with disease. Twenty-one patients (20.2 percent) had died of the disease; 3 patients (2.9 percent) had died of other diseases and these 3 patients were not included in the analysis of the cause of death from disease. The actuarial overall 3-year disease-specific survival rates were 74.2 percent (Fig. 1A). The 3-year overall survival rate of patients with low and high-grade tumors was 85.9 percent and 66.5 percent for the high-grade tumors patients. Three-

Table 1. Clinical and pathologic characteristics of the patients

Variables	No (%)
Age	
- ≥ 60 years	26 (25.0)
- < 60 years	78 (75.0)
Gender	
- Male	48 (46.2)
- Female	56 (53.8)
Site of primary tumor	
- Upper extremity	19 (18.3)
- Lower extremity	74 (71.2)
- Head, neck and trunk	11 (11.6)
Tumor size	
- < 5 cm	6 (5.8)
- ≥ 5 cm	98 (94.2)
Tumor grade	
- Low	26 (25.0)
- High	78 (75.0)
Margin	
- Free	64 (61.5)
- Closed	20 (19.2)
- Not free	17 (16.3)
- Others	3 (2.9)
Presentation	
- Primary	63 (60.6)
- Recurrent	26 (25.0)
- Others	15 (14.4)
Surgery	
- Yes	100 (96.2)
- No	4 (3.8)
Radiation therapy	
- Yes	51 (49.0)
- No	53 (51.0)
Local recurrence	
- Yes	26 (25.0)
- No	78 (75.0)
Metastasis	
- Yes	29 (27.9)
- No	70 (67.3)
Metastasis at initial presentation	5 (4.8)
Histopathology	
- Malignant fibrous histiocytoma	21 (20.2)
- Liposarcoma	21 (20.2)
- Synovial sarcoma	13 (12.5)
- Fibrosarcoma	8 (7.7)
- Leiomyosarcoma	8 (7.7)
- Malignant peripheral nerve sheath tumor	5 (4.8)
- Malignant hemangiopericytoma	5 (4.8)
- Rhabdomyosarcoma	3 (2.9)
- Others	20 (19.2)

year disease-free survival rates were 58.3 percent. Because only 3 patients had died of other diseases, the overall survival and the disease-specific survival were nearly similar. Patients with older age, high-grade tumor, positive surgical margin and occurrence of distant metastasis after initial treatment were associated with decreased overall survival in univariate analysis. Gender, tumor site, tumor size, occurrence of local recurrence and radiation therapy were not associated with decreased survival. These statistical analyses are summarized in Table 2.

Furthermore, if disease-specific survival data was shown according to surgical margin, after partitioning by tumor grade (low and high-grade), the detrimental effect of the high-grade was evident (Fig. 2). For the low-grade group, the 3-year disease-specific survival was not significantly different for the positive surgical margin group compared with the negative surgical margin group ($p = 0.64$). This finding is in contrast to that of the high-grade group, in which the comparative survival rate was significantly different between the positive surgical margin (38.6 percent survival) and the negative surgical margin group (70.0 percent survival) ($p = 0.007$).

Results of a stepwise Cox multiple regression analysis of prognostic factors for overall survival are shown in Table 3. Only those variables that had prognostic significance for overall survival in the univariate analysis were included in the multivariate model. Patients with the 2 prognostic factors of positive surgical margin and occurrence of distant metastasis after initial treatment had a 28-fold increased risk of dying from the disease compared with patients with none of these factors.

Local Disease-Free Survival

Of 104 patients, 22 patients (21.2 percent) had local recurrence and 4 patients (3.8 percent) had relapse of disease near the primary site. The actuarial 3-year local disease-free survival rates were 69.1 percent (Fig.1B). Patients with a positive surgical margin were at the greatest risk for local recurrence in a univariate analysis. These statistics are summarized in Table 4. Age, gender, tumor location, tumor size, tumor grade and radiation therapy were not prognostic factors in predicting local control. The actuarial local disease-free survival in positive margin and negative margin patients are shown (Fig. 3). The 3-year local disease-free survival was 76.1 percent in margin-negative patients and 24.2 percent in margin-positive patients ($p = 0.002$).

A stepwise Cox multiple regression analysis of prognostic factors for local control was performed. Only positive surgical margin was the factor that influenced local control of the disease. Patients with

Table 2. Disease-specific survival by variables

Variables	N	3-yr survival (%)	p-value*
Age			
- ≥ 60 years	26	45.8	0.004
- < 60 years	78	71.4	
Gender			
- Male	48	63.0	0.81
- Female	56	67.2	
Site of primary tumor			
- Extremity	93	66.7	0.62
- Head, neck and trunk	11	54.6	
Tumor size			
- < 5 cm	6	66.7	0.79
- ≥ 5 cm	98	65.3	
Tumor grade			
- Low	26	80.8	0.04
- High	78	60.0	
Margin			
- Negative	84	69.9	0.01
- Positive	17	44.4	
Presentation			
- Primary	63	59.3	0.96
- Recurrent	26	66.7	
Local recurrence			
- Yes	26	40.9	0.06
- No	78	72.1	
Metastasis			
- Yes	29	24.6	<0.0001
- No	70	81.9	
Radiation therapy			
- Yes	51	68.6	0.27
- No	51	62.0	

* Log-rank comparison of survival curve

Table 3. Stepwise Cox regression analysis of prognostic variables for overall survival

Factors	p	Relative risk	95% confidence interval for relative risk
Occurrence of metastasis	<0.0001	7.2	2.7-18.8
Positive surgical margin	0.004	3.9	1.5-10.0

positive surgical margins had a 3.5-fold higher risk of a local recurrence than did negative margin patients. The 95 percent confidence interval for this relative risk was 1.5-7.8. The influence of margins on local recurrence was statistically significant (p = 0.003).

Distant Metastasis-Free Survival

At time of analysis, 29 patients (27.9 percent) developed distant metastasis after initial treatment. Five patients (4.8 percent) had already developed metastasis at initial presentation; these patients were not included in analysis of distant metastasis-free survival. The actuarial 3-year distant metastasis-free survival rates were 66.7 percent (Fig. 1C). Patients with high-grade and older-age (≥ 60 years) were at greatest risk for distant metastasis in a univariate analysis (p = 0.03

Table 4. Local disease-free survival by variables

Variables	N	3-yr local disease-free survival (%)	p-value*
Age			
- ≥ 60 years	26	76.9	0.49
- < 60 years	78	76.9	
Gender			
- Male	48	77.1	0.94
- Female	56	76.7	
Site of primary tumor			
- Extremity	93	77.4	0.80
- Head, neck and trunk	11	72.7	
Tumor size			
- < 5 cm	6	66.7	0.84
- ≥ 5 cm	98	77.6	
Tumor grade			
- Low	26	76.9	0.61
- High	78	76.9	
Margin			
- Negative	84	82.1	0.001
- Positive	17	55.0	
Presentation			
- Primary	63	74.1	0.65
- Recurrent	26	74.0	
Radiation therapy			
- Yes	51	82.4	0.27
- No	51	71.7	

* Log-rank comparison of survival curve

and p = 0.01, respectively). These results are shown in Table 5. Tumor site, tumor size, positive surgical margin and occurrence of local recurrence were not significant prognostic factors in predicting distant metastasis.

A stepwise Cox multiple regression analysis of prognostic factors for distant disease-control was performed. Having an age ≥ 60 years old was the only factor that influenced distant control. Patients with age ≥ 60 years old had a 2.5-fold higher risk of a distant metastasis than did patients with an age < than 60 years. The 95 percent confidence interval for this relative risk was 1.2-5.5. The influence of age on distant metastasis was statistically significant (p = 0.01).

Discussion

The present series demonstrated the outcomes of the patients over a median follow-up time of 24.5 months. The actuarial disease-specific survival rates at 3-years was 74.2 percent. The 3-year overall survival rate of patients with low and high-grade tumors was 85.9 percent and 66.5 percent respectively. In univariate analysis, 4 prognostic variables for disease-specific survival were identified: high-grade tumor, positive surgical margin, older age group patients (≥ 60 years) and occurrence of distant metastasis after initial treatment. Multivariate analysis revealed occurrence of distant metastasis after initial treatment and positive surgical margin to be the dominant variables influencing disease-specific survival. Positive surgical margin also predicted development of local recurrence. Development of local recurrence did not influence distant metastasis-free and disease-specific survival. High-grade tumor and age 60 years or older at the time of diagnosis did predict the development of distant metastasis on univariate analysis. Only being in the ≥ 60 years old age group at the time of diagnosis was the factor that influenced metastasis-free survival on multivariate analysis.

The correlation between positive surgical margin and local recurrence of soft-tissue sarcoma has been well documented[4-9]. However, the specific role of margins on metastasis-free and disease-specific

Table 5. Distant metastasis-free survival by variables

Variables	N	3-yr local survival (%)	p-value*
Age			
- ≥ 60 years	26	61.5	0.02
- < 60 years	78	78.2	
Gender			
- Male	48	68.7	0.21
- Female	56	78.6	
Site of primary tumor			
- Extremity	93	75.2	0.39
- Head, neck and trunk	11	63.6	
Tumor size			
- < 5 cm	6	83.3	0.52
- ≥ 5 cm	98	73.5	
Tumor grade			
- Low	26	84.6	0.05
- High	78	70.5	
Margin			
- Negative	84	75.0	0.53
- Positive	17	70.0	
Presentation			
- Primary	63	71.0	0.89
- Recurrent	26	77.8	
Local recurrence and relapse			
- Yes	26	59.1	0.14
- No	78	78.1	

* Log-rank comparison of survival curve

survival remains controversial. Some evidence supports the idea that having a positive surgical margin does not influence both metastasis-free and disease-specific survival[5-7,12,13]. Some do support this correlation and believe that positive surgical margin is reflective of more aggressive tumor biological behavior, and leaving residual microscopic disease represented a nidus for tumor dissemination[14-18]. The findings in the present study suggested that margins were important predictors of local recurrence and disease-specific death in high-grade sarcoma. For the low-grade group, the positive surgical margin group had better disease-specific survival than the negative surgical margin group. This result had no statistical significance which might reflect the small population of the low-grade group.

Although the present study demonstrated that positive surgical margin predicted the development of subsequent mortality, the development of local recurrence did not influence disease-specific survival or even distant metastasis. The present findings were similar as those of previous prospective and retrospective studies which reported that the improvement of local control did not affect the overall survival rate[4,14,19-24]. Brennan et al. found the use of adjuvant radiation by the brachytherapy technique in soft-tissue sarcomas of the extremity had shown a decrease in local recurrence, but no impact on survival[18]. Despite these findings, the authors still emphasize the importance of achieving negative surgical margin, because leaving residual microscopic disease might establish subclinical distant metastasis and lead to decreasing disease-specific survival[24].

The influence of tumor grade on distant metastasis-free and disease-specific survival has been well established[7,13,14,25,26]. The results of the present study also confirmed this correlation in univariate analysis. However, in multivariate analysis, tumor grade, positive surgical margin and occurrence of metastasis after initial treatment seemed to be less important in predicting distant metastasis and mortality than being aged 60 years or over.

In many studies, a large size sarcoma (≥ 5 centimeters) predicted the development of local recurrence and mortality while small size (< 5 centimeters)

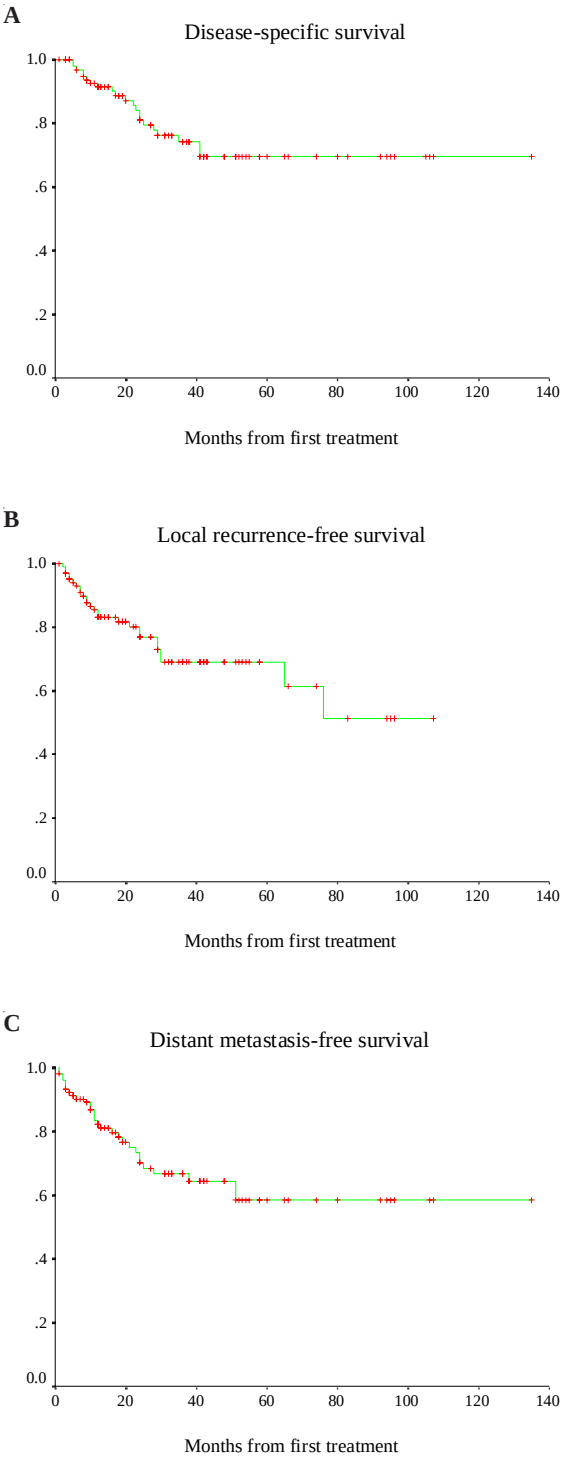

Fig. 1 Actuarial product limit estimations for overall group (104 cases). (A) Disease-specific survival. (B) Local recurrence-free survival. (C) Distant metastasis-free survival

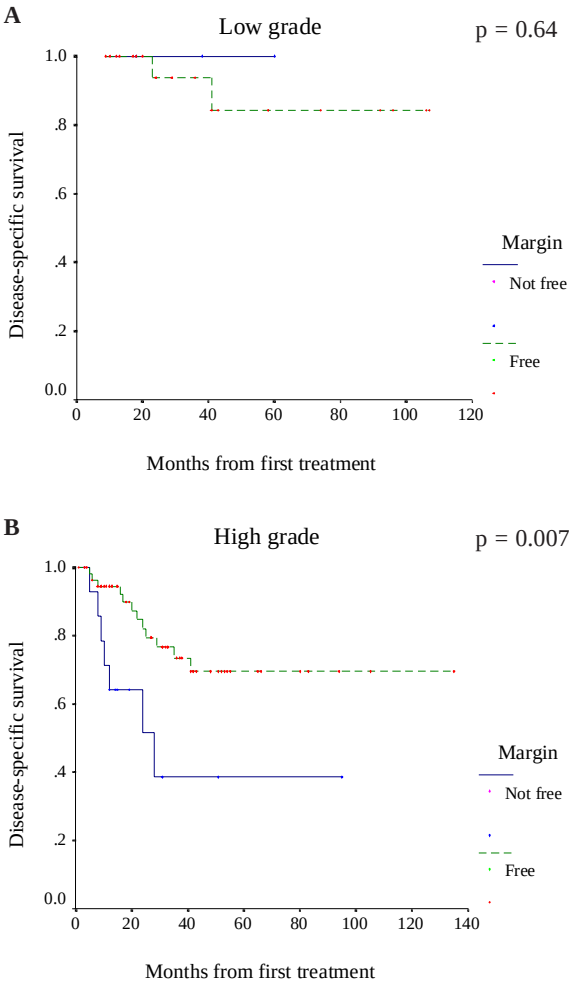

Fig. 2 Disease-specific survival for overall patients according to positive or negative surgical margin, the data are shown by tumor grade; low-grade (A) high grade (B) For the low-grade group survival was not different for the positive compared to the negative surgical margin (p = 0.64), however in the high-grade group, survival rates differed significantly between the positive and the negative surgical margin (p = 0.007). (comparison by the log rank statistics)

had a promising outcome[7,13-14,27]. However, patients with a tumor < 5 centimeters in the present study were only 5.8 percent of all patients. This might be why tumor size did not show statistically different results relating to local recurrence-free, distant metastasis-free and disease-specific survival.

The treatment of soft-tissue sarcoma is a complex problem requiring knowledge and skill in many aspects of oncologic care. A number of factors determine the disease-specific, local recurrence and distant

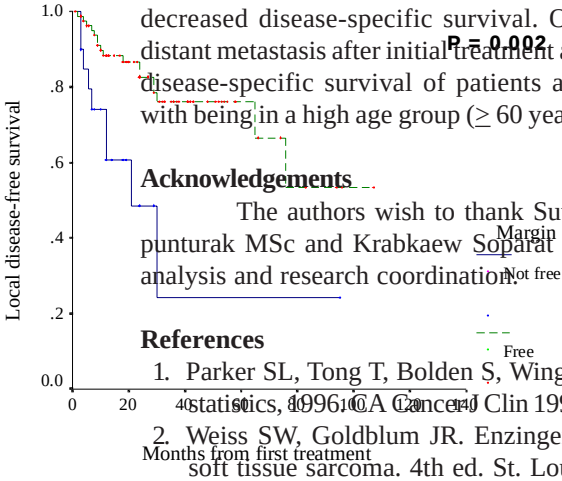

Fig. 3 Local disease-free survival in the patients with positive versus negative margin (p = 0.002)

metastasis-free survival, including surgical margin, tumor grade, patient's age and occurrence of distant metastasis after initial treatment. These results reemphasize the importance of obtaining negative surgical margin, where uncontrolled local disease predicted the occurrence of local recurrence of the tumor and decreased disease-specific survival. Occurrence of distant metastasis after initial treatment and decreased disease-specific survival of patients are associated with being in a high age group (≥ 60 years).

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ผลการรักษาและปัจจัยที่มีผลต่อการพยากรณ์โรคในผู้ป่วยที่เป็นมะเร็งของเนื้อเยื่อเกี่ยวพัน

ปิยะ เกียรติเสวี, อภิชาติ อัศวมงคลกุล, ระพินทร์ พิมลศานติ์, สารเนตร ไวคกุล, สุชาติ เบญจรัศมีโรจน์

การศึกษาย้อนหลังเพื่อดูผลการรักษาและปัจจัยที่มีผลต่อการพยากรณ์โรคในผู้ป่วยที่เป็นมะเร็งของเนื้อเยื่อเกี่ยวพันบริเวณรยางค์, ลำตัว, ศีรษะและลำคอ การศึกษานี้ทำในผู้ป่วย 104 ราย ประกอบด้วยเพศชาย 48 ราย และเพศหญิง 56 ราย ซึ่งมีอายุเฉลี่ย 44.5 ปี ผู้ป่วย 78 ราย เป็นมะเร็งชนิด high-grade โดยมากพบที่บริเวณรยางค์ ผู้ป่วย 100 ราย ได้รับการรักษาโดยการผ่าตัดและมีผู้ป่วย 51 ราย ได้รับการฉายรังสีรักษาร่วมด้วย จากการเฝ้าติดตามผู้ป่วยภายหลังการรักษานานโดยเฉลี่ย 24.5 เดือน พบว่ามีอัตราการเกิดโรคซ้ำ 25 เปอร์เซ็นต์ และมีการแพร่กระจายของโรคไปยังอวัยวะอื่น ๆ 27.9 เปอร์เซ็นต์ พบอัตราการรอดชีวิตของผู้ป่วยที่ 3 ปี เท่ากับ 74.2 เปอร์เซ็นต์ จากการศึกษาทางสถิติพบว่าการผ่าตัดเนื้องอกออกไม่หมด และการเกิดการแพร่กระจายของโรคไปยังอวัยวะอื่น ๆ มีผลต่ออัตราการรอดชีวิตของผู้ป่วยอย่างมีนัยสำคัญ และพบว่าการผ่าตัดเนื้องอกออกไม่หมดจะเพิ่มโอกาสการเกิดโรคซ้ำ รวมทั้งผู้ป่วยสูงอายุ (≥ 60 ปี) มีโอกาสเกิดการแพร่กระจายของโรคมากกว่า การศึกษาครั้งนี้ ยืนยันถึงความสำคัญของการผ่าตัดนำมะเร็งเนื้อเยื่อเกี่ยวพันเพื่อให้ได้ขอบเขตที่กว้างเพียงพอ ซึ่งจะช่วยลดอัตราการเกิดโรคซ้ำและเพิ่มอัตราการรอดชีวิตของผู้ป่วย