Analysis of Pretreatment Prognostic Factors in Stage IIB Carcinoma of the Uterine Cervix

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From March 1979 through December 1986, 232 previously untreated patients with invasive carcinoma of the uterine cervix stage IIB were treated at the Department of Therapeutic Radiology, Seoul National University Hospital. The patients studied were staged according to the FIGO recommendations and the majority of patients were treated with external beam whole pelvis radiation and intracavitary radiation. Pretreatment parameters, including physical examination findings, blood parameters, prior medical illnesses, histology and abdomino-pelvic CT findings were studied, employing univariate and multivariate analyses to identify the potentially significant prognostic factors on locoregional control, disease free survival and overall survival. Histology, extent of parametrial involvement on physical examination and paraaortic lymph node metastasis on CT were found to have prognostic significance in the carcinoma of uterine cervix stage IIB.

Key Words: Cervix cancer, Stage IIB, Prognostic factors, Radiation therapy

INTRODUCTION

Radiation therapy continues to be the mainstay of treatment for patients with stage IIB carcinoma of the uterine cervix. Since 1984, although three studies of cervix cancer including the results of radical radiotherapy[1], post operative radiotherapy[2] and treatment of recurrent cervix cancer[3] were reported from our department, analysis of pretreatment prognostic factors was lacking.

A great deal of information is available emphasizing the prognostic importance of numerous historical factors, physical examination findings, histopathological results, initial laboratory findings and CT findings on local control and survival in patients with invasive carcinoma of the uterine cervix[4~23]. But the possible interactions between these parameters make the influence of any solitary factor on patient survival difficult to interpret unless all other pertinent factors are controlled for. Therefore, a multivariate analysis using a Cox's regression model was undertaken in an attempt to identify the potentially important prognostic factors in stage IIB cervix cancer and the results are compared with previously reported studies.

MATERIALS AND METHODS

From March 1979 through December 1986, a total of 510 patients with previously untreated invasive carcinoma of the uterine cervix received radiation therapy with curative intent at the Department of Therapeutic Radiology, Seoul National University Hospital.

Pretreatment evaluation consisted of medical history, physical examination, complete blood count, blood chemistry, chest X-ray, intravenous pyelogram, cystoscopy and sigmoidoscopy. From May 1981, abdomino-pelvic CT was added. The patients were staged according to the International Federation of Gynecology and Obstetrics (FIGO) system[24]. Two hundred and sixty four patients with stage IIB carcinoma were identified and 32 patients were excluded from this study because of incomplete treatment. Therfore, 232 patients form the base of this report.

The treatment was designed to deliver combined external beam and one or two courses of intracavitary radiation therapy. The external beam therapy was given with ^{60}CO gamma ray or 10 MV X-ray and 4000~5000 cGy was generally given to the whole pelvis, 175~200 cGy daily and 5 days per week. AP and PA portals or a four field box technique was used. Following external beam therapy, the intracavitary applications using the Fletcher-Suit applicator were performed to deliver a total

dose of 8000~8500 cGy to point A. Additional 300 ~1400 cGy external beam therapy, as necessary, was given to the involved parametrial area.

Intracavitary theapy was not possible because of anatomic reasons and extensive residual tumors in 11 patients. They received additional 1500~2000 cGy of external beam therapy with anterior, right posterior oblique and left posterior oblique portals, and a total dose to the cervix and parametrial areas was 6500~7000 cGy.

The base of follow-up was the date of initiation of radiation therapy and median follow-up period was 81 months ranging from 2 to 146 months. The treatment failures were classified as locoregional recurrence (cervix, vagina, parametrium and other intrapelvic sites) or distant metastasis. Locoregional control was measured from the date of initiation of treatment to the date of the first locoregional recurrence or the date of last follow-up. Disease free survival was the initiation of treatment to the date of first relapse or death or last follow-up. In patients who did not achieve complete response, the interval was regarded as zero. Overall survival was measured from the date of the

initiation of treatment to the date of death caused by cervix cancer or last follow-up. Death from other causes was regarded as consoring.

Survival calculation was performed using life table method[25], and generalized Wilcoxon test[26] was used for univariate analysis and Cox proportional hazard model[27] was used for multivariate analysis.

RESULTS

Actuarial locoregional control rate was 70.1%, disease free survival was 60.3%, and overall survival was 67.0% at 5 years in the 232 stage IIB cervix cancer patients.

Univariate analysis of pretreatment factors for stage IIB cervix cancer is depicted in Table 1 and 2. Several pretreatment factors has prognostic significance with respect to locoregional control, disease free survival and overall survival in univariate analysis, i.e., histology, parametrial involvement status on physical examination and paraaortic lymph node status on CT. Patients with squamous histology has better locoregional control (p=0.

Table 1. Prognostic Factors, Univariate Analysis (I)

Factor	No. of patients(%)	5-year LRC(%)	P value	5-year DFS(%)	P value	5-year OS(%)	P value
Age (years)			NS		0.06		NS
<50	89(38)	65		53		64	
≥50	143(62)	73		64		69	
ECOG score			NS		NS		NS
0~1	178(93)	72		61		67	
2~4	14(7)	71		71		76	
No. of pregnancies			NS		NS		NS
<5	50(30)	66		60		64	
≥5	117(70)	68		58		65	
History of diabetes			NS		NS		NS
absent	191(95)	71		61		67	
present	11(5)	63		63		71	
History of hypertension			NS		NS		NS
absent	175(90)	70		60		66	
present	20(10)	74		69		73	
Hemoglobin (gm/dL)			NS		NS		NS
<10	20(9)	69		53		65	
≥10	209(91)	70		61		67	
Neutrophil count (/mm³)			NS		NS		NS
<4000	59(42)	71		63		67	
≥4000	83(58)	61		51		60	
Lymphocyte count (/mm³)			NS		NS		NS
<2000	71(50)	71		62		69	
≥2000	71(50)	59		50		57	

NS: not significant

Table 2. Prognostic Factors, Univariate Analysis (II)

Factor	No. of patients(%)	5-year LRC(%)	P value	5-year DFS(%)	P value	5-year OS(%)	P value
Histology			0.01		0.01		0.01
squamous	218(95)	72		62		69	
non-squamous	12(5)	23		21		21	
Tumor shape			0.09		NS		NS
infiltrative	35(21)	58		51		54	
non-infiltrative	135(79)	71		61		70	
Tumor size			NS		NS		NS
<4	94(44)	73		62		71	
≥4	122(56)	66		56		63	
Parametrium thickening			0.01		0.01		0.01
unilateral	177(76)	74		64		73	
bilateral	55(24)	55		47		50	
CT findings							
pelvic LN			NS		NS		0.08
normal	116(75)	72		61		71	
enlarged	39(25)	62		58		58	
paraaortic LN			0.01		0.01		0.01
normal	147(95)	71		62		70	
enlarged	8(5)	33		25		29	
parametrium			NS		NS		NS
normal	63(41)	69		60		70	
invaded	92(59)	69		60		67	
uterine body			NS		NS		NS
invasion (−)	147(95)	68		59		66	
invasion (+)	8(5)	88		74		88	
bladder			NS		NS		NS
invasion (−)	144(93)	69		60		68	
invasion (+)	11(7)	71		60		70	
rectum			NS		NS		NS
invasion (−)	146(94)	70		61		69	
invasion (+)	9(6)	53		53		53	

Table 3. Multivariate Analysis of Locoregional Failure excluding CT Findings   (N=226)

Factor	Coefficient	Standard error	Relative risk	P value
Age				
≥50/<50	−0.2992	0.2610	0.74	NS
Histology				
non-squamous /squamous	0.9506	0.3899	2.59	<0.05
Tumor shape				
infiltrative /non-infiltrative	0.4225	0.3140	1.53	NS
Tumor size (cm)				
≥4/<4	0.1441	0.2679	1.16	NS
Hemoglobin (gm/dl)				
<10/≥10	−0.3394	0.4489	0.71	NS
PM* thicking				
bilateral /unilateral	0.6043	0.2706	1.83	<0.05

*PM: parametrium

004), disease free survival (p=0.009) and overall survival (p=0.002) than patients with nonsquamous histology. Patients with unilateral parametrial involovment on physical examination has superior results to bilateral parametrial involvment in terms of locoregional control (p=0.004), disease free survival (p=0.014) and overall survival (p=0.002). Patients who had paraaortic lymph node enlargement on CT showed worse locoregional control (p=0.005), disease free survival (p=0.002) and overall survival (p=0.005). Age, ECOG performance status, number of pregnancy, presence or absence of diabetes or hypertension, tumor shape and size on physical examination, pelvic lymph node status on CT, parametrial status on CT, uterus,

bladder or rectal invasion on CT, initial hemoglobin level, neutrophil count and lymphocyte count did not affect the results.

In multivariate analysis, as the abdomino-pelvic CT was performed in only 155 patients, analysis was performed in two ways - excluding CT findings and including CT findings. Multivariate analyses of pretreatment factors for stage IIB cervix cancer are depicted from Table 3 to Table 8. In analysis excluding CT findings (N=226), histology and parametrial involvement status on physical examination showed significant relative risk value in terms of locoregional control and overall survival and marginally significant relative risk value in disease free survival. In another analysis including

Table 4. Multivariate Analysis of Disease Free Survival excluding CT findings   (N=226)

Factor	Coefficient	Standard error	Relative risk	P value
Age				
≥50/<50	−0.2720	0.2278	0.76	NS
Histology				
non-squamous	0.7158	0.3805	2.05	0.05<P<0.1
/squamous				
Tumor shape				
infiltrative	0.2335	0.2912	1.26	NS
/non-infiltrative				
Tumor size (cm)				
≥4/<4	0.0942	0.2317	1.09	NS
Hemoglobin (gm/dl)				
<10/≥10	−0.0873	0.3738	0.91	NS
PM thicking				
bilateral	0.4570	0.2436	1.58	0.05<P<0.1
/unilateral				

Table 5. Multivariate Analysis of Overall Survival excluding CT findings   (N=226)

Factor	Coefficient	Standard error	Relative risk	P value
Age				
≥50/<50	−0.0928	0.2615	0.91	NS
Histology				
non-squamous	0.9294	0.4143	2.53	<0.05
/squamous				
Tumor shape				
infiltrative	0.2381	0.3212	1.27	NS
/non-infiltrative				
Tumor size (cm)				
≥4/<4	0.3409	0.2663	1.41	NS
Hemoglobin (gm/dl)				
<10/≥10	−0.6110	0.4881	0.54	NS
PM thicking				
bilateral	0.7721	0.2621	2.16	<0.05
/unilateral				

Table 6. Multivariate Analysis of Locoregional Failure including CT findings   (N=155)

Factor	Coefficient	Standard error	Relative risk	P value
Age				
≥50/<50	−0.0556	0.3283	0.95	NS
Histology				
non-squamous /squamous	1.4443	0.4443	4.24	<0.05
Tumor shape				
infiltrative /non-infiltrative	0.4253	0.3736	1.53	NS
Tumor size (cm)				
≥4/<4	0.1283	0.3267	1.14	NS
Hemoglobin (gm/dl)				
<10/≥10	−0.1554	0.6317	0.85	NS
PM thicking				
bilateral /unilateral	0.4529	0.3431	1.57	NS
CT finding				
pelvic LN* (+)/(−)	0.1429	0.3512	1.15	NS
PAN** (+)/(−)	1.1897	0.5321	3.29	<0.05

*LN: lymph node   **PAN: paraaortic node

Table 7. Multivariate Analysis of Disease Free Survival including CT findings   (N=155)

Factor	Coefficient	Standard error	Relative risk	P value
Age				
≥50/<50	−0.1629	0.2896	0.84	NS
Histology				
non-squamous /squamous	1.2999	0.4295	3.67	<0.05
Tumor shape				
infiltrative /non-infiltrative	0.1978	0.3563	1.22	NS
Tumor size (cm)				
≥4/<4	0.0789	0.2883	1.08	NS
Hemoglobin (gm/dl)				
<10/≥10	0.3259	0.4721	1.38	NS
PM thicking				
bilateral /unilateral	0.4381	0.3055	1.55	NS
CT finding				
pelvic LN (+)/(−)	−0.0210	0.3189	0.98	NS
PAN (+)/(−)	1.3412	0.4805	3.82	<0.05

CT findings (N=155), histology and paraaortic lymph node status on CT were prognostically significant for locoregional control, disease free survival and overall survival. Parametrial involvement status on physical examination was significant only for overall survival.

DISCUSSION

The various prognostic and pretreatment factors that affect control of disease in patients with uterine cervix cancer treated with radiation alone, when analyzed one at a time, have been reported. However, the influence of individual parameters on

Table 8. Multivariate Analysis of Overall Survival including CT findings   (N=155)

Factor	Coefficient	Standard error	Relative risk	P value
Age				
≥50/<50	−0.1042	0.3212	0.90	NS
Histology				
non-squamous	1.4697	0.4716	4.35	<0.05
/squamous				
Tumor shape				
infiltrative	0.3185	0.3834	1.38	NS
/non-infiltrative				
Tumor size (cm)				
≥4/<4	0.2783	0.3249	1.32	NS
Hemoglobin (gm/dl)				
<10/≥10	−0.2696	0.6369	0.76	NS
PM thicking				
bilateral	0.7163	0.3307	2.05	<0.05
/unilateral				
CT finding				
pelvic LN (+)/(−)	0.3300	0.3283	1.39	NS
PAN (+)/(−)	1.2582	0.5182	3.52	<0.05

locoregional control, disease free survival and overall survival in cervix cancer employing a multivariate analysis has not been made clear yet.

There have been reports using Cox's model to define prognostic factors in locally advanced cervix cancer. Stehman and coworkers[28] in Gynecologic Oncology Group evaluated 626 patients treated at 31 participating institutes, all of whom had underwent operative assessment of the paraaortic lymph node; they showed patient age, performance status, paraaortic lymph node status, tumor size, pelvic node status, clinical stage and bilateral extension to be significantly associated with survival. Similarly, Kapp et al[29] reviewed 910 patients treated over three decades and found FIGO clinical stage to be the most significant prognostic factor in predicting survival. A number of other factors including patient's age, histologic finding, hematocrit level, parity, neutrophil count, uterine position, history of diabetes and intact uterus were also significant.

Present study was performed on the cases of limited stage(IIB) treated at one institute with uniform protocol by very limited number of radiotherapist in a relatively short period, and data from this kind of study should be more valuable.

1. Histology

Interest in nonsquamous carcinoma of uterine cervix, especially adenocarcinoma, has been growing, in part because of an apparent increase in the proportion of patients presenting with glandular neoplasms during the past decades[4,5]. Several authors have argued that the survivals of patients treated for adenocarcinoma and squamous cell carcinoma are comparable. Grigsby et al[6]. compared the survival of 101 patients with adenocarcinoma with that of 1138 patients with squamous cell carcinoma treated during the same period and found no significant difference in overall disease free survival. Other investigators have attemped to make comparisons with matched squamous controls but have failed to find a significant difference, perhaps because small numbers of patients were studied and because of difficulty of matching patients whose important prognostic variables may differ[7,8]. In contrast, Pejovic et al.[9], in a series of a total of 1863 patients with carcinoma of the cervix, 7% of whom had adenocarcinoma, reported lower survival rates in patients with adenocarcinomas as compared to those with squamous cell carcinoma. In our results, nonsquamous histology formed 5.2% (12/230) of stage IIB patients, which consisted of adenocarcinoma (2.6%, 6/230), adenosquamous carcinoma (1,74%, 4/230), and mixed carcinoma (0.87%, 2/230), and this group altogether had statistically significant adverse prognosis in terms of locoregional control, disease free survival and overall survival in univariate analysis; this trend is noticed for locoregional control, disease free survival and overall survival in multivariate analysis, including CT findings and for

locoregional control and overall survival in multivariate analysis excluding CT findings.

2. Parametrium

In our results, unilateral parametrial disease on physical examination is associated with significantly better overall survival compared to bilateral parametrial disease in a Cox's regression analysis controlling for the effect of other factors such as age, histology, tumor shape, tumor size, initial hemoglobin level, pelvic and paraaortic lymph node status on CT.

Sinistrero et al[10]. separated stage IIB disease into unilateral versus bilateral parametrium but failed to show the prognostic value with respect to survival analyzing 98 stage IIB patients. In contrast, Lanciano et al.'s patterns of care study of squamous cell carcinoma of the uteine cervix[11] showed that unilateral parametrial disease had been associated with significantly improved pelvic control and survival compared to bilateral parametrial disease for 413 stage IIB patients. As there is a tendency of worse prognosis for bilateral parametrial involvement, a measure to increase the radiation dose to parametrium and pelvic sidewall such as interstitial implant may be needed especially for bilateral parametrial invasion.

3. Paraaortic Lymph Node

Cervix cancer frequently metastasizes to regional lymph nodes in the pelvis followed by metastases to paraaortic nodes. The importance of detecting lymph node metastases outside of the pelvis relates to the inability to cure such patients using conventional radiotherapy directed to the pelvis alone and an overall poor prognosis even when recognized. Paraaortic lymph node metastases can be evaluated by several techniques including lymphangiography, CT and surgical approach. Although there are some argues on detecting the pelvic or paraaortic lymph node metastases by CT, we evaluated the paraaortic lymph node status by CT and the efficiency was discussed by Kim et al.[30], already. The prognostic importance of paraaortic lymph node metastasis has been proven especially in surgical series[12~15,28]. Podczaski and coworkers[12], evaluating 155 patients, found paraaortic nodal status to be significant predictors of survival. Similarly, Stehman et al in the Gynecologic Oncology Group[28] showed that paraaortic node status is significantly associated with progression-free interval and survival. In this study, the patients showing enlarge-ment of paraaortic lymph node on CT formed only 5.16% (8/155) compared to 6.6%~16.7% usually reported in surgical series[12~15], and this group has adverse prognosis in terms of locoregional control, disease free survival and overall survival.

Survival data for patients with metastases to lymph node along the paraaortic chain is uncertain because long term follow-up of large numbers of such patients has not been reported. Ballon et al. reported 23% 5 year disease free survival in 18 patients[13], Buchsbaum reported 23.8% 5 year survival in 21 patients[14]. Berman et al. reported 25% 3 year survival in 98 patients[15] and Lee et al., 25.7% in 41 patients[31]. Our study for all stage cervix cancer cases of 25 patients who has paraaortic lymph node metastases on CT showed 5 year survival rate of 34%[32], and it is a slightly superior survival rate compared with other previous reports.

4. Tumor Size

Tumor size has been demonstrated to be strongly correlated with pelvic local control and survival following radiation therapy. But our findings failed to support the generally held clinical impression of poorer response of bulky lesions ($\geq$ 4 cm) as opposed to smaller lesions ($<$4 cm). Although many investigators have advocated the use of extrafascial hysterectomy as an adjuvant to irradiation in patients with lesions$\geq$6 cm[16], others pointed out the biases of their reports. For example, in a retrospective review of 128 patients with barrel-shaped lesions greater than 5 cm in diameter, Perez et al.[17] concluded that tumor control with radiation therapy alone is comparable to that with combined treatment if adequate radiation doses are employed.

This study failed to show significance, and it is suggested that as stage IIB carcinoma of uterine cervix has tumors in parametrium in addition to cervix itself, the effect of primary tumor size is less important than in earlier stage disease. Actually in stage IB-IIA patients of our study[33], tumor size was demonstrated to be significant for locoregional control, disease free survival and overall survival.

5. Anemia

It has been our policy in recent years, to transfuse anemic patients so that their hemoglobin levels are higher than or equal to 12 gm% prior to the institution of radiation therapy. Nonetheless, our results in stage IIB did not show any prognostic significance in locoregional control, disease free survival and overall survival not only univariate but

also in multivariate analyses.

Generally, the deleterious effect of anemia on local failures and survival in carcinoma of the uterine cervix has been reported by several investigators[18~22]. Although the mechanism by which the low hemoglobin level adversely effects patient survival may not be clear cut, the existence of an increased percentage of hypoxic, relatively radioresistant tumor cells in anemic patients may help to explain the increased rate of local persistence or recurrence noted in the irradiated patients. Furthermore, the role of blood transfusions in prognosis is unclear and controversial. For some authors, like Buch et al.[18], blood transfusion is beneficial, for others, like Vigario et al.[19] and Evans and Bergsjo[20], it is of no value or even detrimetal in that they increase the rate of recurrence. Although we failed to show significance in stage IIB, hemoglobin concentration before treatment was a prognosticator in our univariate analyses of all stage cervix cancer cases, which is in agreement with many other univariate studies[18,19,29]. However, this prognostic value did not exist in the multivariate analysis, and contradicts other multivariate studies[18,21].

These contradictory findings could be explained, as Girinski et al.[22] pointed out, by the fact that because the hemoglobin concentration in our study was those before transfusions, the effect of transfusions, favorable or unfavorable, should be reflected and that the carcinomas of uterine cervix have a tendency to bleed during treatment. Consequently for the two reasons cited above, the hemoglobin level before treatment in our study was less likely to reflect hemoglobin levels throughout treatment and therefore could not be a prognostic factor.

6. Other Factors

Like the factors previously discussed, there are many controversies for other prognostic factors such as age, ECOG performance status, parity, history of diabetes and hypertension, tumor shape, pelvic lymph node and parametrial status on CT, neutrophil count and lymphocyte count which we analyzed[23,28,29]. In our study, these were revealed to be of no significance in stage IIB carcinoma of uterine cervix.

CONCLUSION

Two hundred and thirty two previously untreated patients with stage IIB carcinoma of the uterine

cervix treated with radiation therapy were analyzed. Present study was performed on the cases of limited stage (IIB) treated at one institute with uniform protocol by very limited number of radiotherapists in a relatively short period. Histology, extent of parametrial involvement on physical examination and paraaortic lymph node metastasis on CT were noted to have prognostic significance in stage IIB carcinoma of the uterine cervix.

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＝ 국문초록 ＝

자궁경부암 IIB 병기에서의 치료전 예후 인자의 분석

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1979년 3월부터 1986년 12월까지 과거에 아무런 치료를 받지 않은 자궁경부암 IIB 병기 환자 232 명을 서울대학병원 치료방사선과에서 치료하였다.

대상 환자들은 FIGO 방식으로 병기가 결정되었으며, 대다수의 환자에게 골반 외부 방사선 조사 및 강내 조사가 병용되어 치료되었다. 이학적 검사소견, 혈액 검사소견, 내과적 질환의 과거력, 조직학 적 소견 및 복부-골반 전산화단층촬영 소견등의 치료전 인자들이 분석되었으며 이들 인자들의 5년 국 소 치료율, 5년 무병 생존율 및 5년 생존율 등에 대한 잠재적인 예후적 유의성을 밝히기 위해 단변수 분석과 다변량 분석을 시행하였다. 조직학적 소견, 자궁내진시 자궁방결합 조직의 침윤, 전산화단층 촬영상 대동맥 임파절의 전이등이 자궁경부암 IIB 병기에서 예후적 유의성을 갖는 것으로 판명되었 다.