Analysis of Pretreatment Prognostic Factors in Locally Advanced Carcinoma of the Uterine Cervix

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To identify pretreatment prognostic factors in locally advanced carcinoma of the uterine cervix, retrospective analysis was undertaken of 154 patients treated with curative radiation therapy at Seoul National University Hospital, from March 1979 through December 1986. According to FIGO classification, eight patients were stage IIIA, 134 were stage IIIB, and 12 were stage IVA. Five year locoregional control rate was 58%, 51%, and 27% in stage IIIA, IIIB, and IVA, respectively. Five year disease free survival was 57%, 40%, and 25% for each stage respectively. Five year overall survival was 67%, 51%, and 33% in stage IIIA, IIIB, and IVA, respectively.

In univariate analysis, fewer than or equal to four of pregnancies, initial hemoglobin of lower than 10 g%, and pelvic sidewall invasion on CT were associated with poor locoregional control. Number of pregnancies, initial hemoglobin level, obstructive uropathy on intavenous pyelography (IVP), pelvic lymph node (LN) status on CT, and pelvic sidewall invasion on CT were significant factors in disease free survival. In terms of overall survival, pelvic sidewall invasion on CT and bladder invasion on CT were prognostically significant.

In multivariate analysis, no factor was found to affect locoregional control and pelvic LN status was a sole significant factor affecting disease free survival. In terms of overall survival, the size of primary tumor was a significant prognosticator.

Key Words: Cervix cancer, Stage III & IV, Prognostic factor, Radiation therapy

INTRODUCTION

Radiation therapy continues to be the treatment of choice for patients with locally advanced carcinoma of the uterine cervix. There have been reports[1~7] on analysis of prognostic factors in this group of patients. But most of those studies were done on patients treated over a long time period or pateints treated at many centers. This retrospective study was carried out to identify the prognostic significance of various pretreatment factors in patients with stage IIIA, IIIB, and IVA carcinomas of the uterine cervix treated in one institute in a same fashion in a relatively short time period.

MATERIALS AND METHODS

We reviewed the results of treatment in 198 newly diagnosed patients with clinical stage IIIA, IIIB, and IVA carcinoma of the uterine cervix who were treated with curative radiation therapy at Seoul National University Hospital from March 1979 through December 1986. Of them, 44 patients who had not undertaken the planned radiotherapy completely were exluded from the analysis.

All the patients were initially evaluated with physical examination and pretreatment staging work-ups including complete blood count, blood chemistry, chest X ray, IVP, sigmoidoscopy, and cystoscopy. As an ancillay study, abdomino-pelvic CT became available in May 1981 and was performed in 100 patients thereafter. All the patients were staged according to the recommendations of the International Federationn of Gynecology and Obstetrics (FIGO) classification system[8]. Eight patients were in stage IIIA, 134 patients were in stage IIIB, and 12 patients were in stage IVA.

Of the 154 patients analyzed, 131 patients were treated with external beam radiotherapy followed by one or two courses of intracavitary radiation. In 23 patients, brachytherapy was impossible or seemed to be not appropriate because of poor geometry and/or extensive residual tumor after whole pelvis irradiaton. They received additional external beam radiotherapy with reduced fields. Treatment details have been previously

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reported[9~11]. Treatment modalities according to stage are illustrated in Table 1.

Follow-up ranged from 2 to 140 months (median 72 months). Treatment failures were classified as locoregional recurrence (cervix, vigina, parametrium, and other intrapelvic sites) or distant metastasis (inguinal node, PAN, and other distant sites). Diagnosis of recurrence was established on the basis of clinical and radiologic examination in 85 patients and pathologic evaluation in 6 patients. Locoregional control was measured from date of initiation of treatment to the date of first locoregional recurrence or the date of last follow-up. Period of disease free survival was the time interval to the date of first recurrence or the date of last follow-up. Overall survival was measured from date of initiation of treatment to the date of death from cervix cancer or date of last follow-up. Death from other causes was censored.

Prognostic factors analyzed are stage, age, ECOG performance status, number of pregnancies, history of diabetes and hypertension, initial hemoglobin level, initial neutrophil count, initial

Table 1. Treatment Modality by Stage

Treatment modality	Stage IIIA	IIIB	IVA	Total
EBRT* alone	1	18	4	23
EBRT+ICR				
1 course**	5	90	6	101
2 course	2	26	2	30
Total	8	134	12	154

*External beam radiotherapy
**Number of intracavitary applications

Table 2. Prognostic factors, Univartiate Analysis (I)

Factor	No. of patients (%)	5-year LRC@(%)	5-year DFS#(%)	5-year OS$(%)
Age (year)				
<50	56(37)	47	36	46
≥50	97(63)	51	41	53
ECOG performance score				
0-1	98(81)	49	38	49
2-4	23(19)	43	33	53
No. of pregnancies				
<5	52(47)	39	33	45
≥5	59(53)	56**	48**	58
Diabetes				
absent	128(96)	50	41	54
present	5(4)	60	60	78
Hypertension				
absent	109(87)	51	41	53
present	17(13)	47	40	56
Hemoglobin (g%)				
<10	25(16)	32	24	39
≥10	127(84)	54**	43**	52
Neutrophil count (/mm^3)				
<4000	30(31)	48	35	42
≥4000	66(69)	42	38	52
Lymphocyte count (/mm^3)				
<2000	53(55)	41	33	47
≥2000	43(45)	47	43	51
BUN or creatinine				
normal	125(95)	50	41	52
elevated	6(5)	50	17*	25

@Locoregional control #Disease free survival $Overall survival
* $0.05<p<0.1$ ** $p<0.05$

lymphocyte count, initial level of BUN and creatinine, histology, shape and size of the primary tumor, extent of parametrial involvement, obstructive uropathy on IVP in terms of locoregional control, disease free survival, and overall survival. And CT findings were also included; pelvic LN status, paraaortic node (PAN) status, extent of parametrial invasion, uterine body invasion, bladder invasion, and rectal invasion.

Survival data were obtained using the life table method[12]. Univariate analyses were carried out using the generalized Wilcoxon test[13] and Cox proportional hazard model[14] was used for multivariate analyses.

RESULTS

In univariate analysis, all pretreatment factors were analyzed and the results are summarized in Table 2 and Table 3. Five year locoregional control

Table 3. Prognostic factors, Univariate Analysis (II)

Factor	No. of patients (%)	5-year LRC (%)	5-year DFS (%)	5-year OS (%)
Histology				
squamous	144(96)	50	39	51
non-squamous	6(4)	50	50	50
Tumor shape				
infiltrative	13(9)	50	39	51
non-infiltrative	113(91)	54	46	57
Tumor size				
<4	38(28)	64	40	66
≥4	97(72)	47	41	49*
Pelvic sidewall involvement%				
unilateral	110(82)	51	38	50
bilateral	24(18)	54	46	56
Obstructive uropathy on IVP				
absent	90(65)	53	43	54
present	49(35)	43*	30**	41
CT findings				
pelvic LN				
normal	67(67)	55	47	52
enlarged	33(33)	35	20**	37
paraaortic LN				
normal	88(88)	50	39	49
enlarged	12(12)	33	28	32
pelvic sidewall				
invasion(−)	82(82)	53	43	54
invasion(+)	18(18)	24**	11**	19**
uterine body				
invasion(−)	94(94)	45	35	46
invasion(+)	6(6)	50	50	44
bladder				
invasion(−)	74(74)	50	38	50
invasion(+)	26(26)	41*	34	40**
rectum				
invasion(−)	77(77)	50	38	51
invasion (+)	23(23)	39	35	35

%Analyzed patients with stage IIIB disease *0.05<p<0.1 **p<0.05

rate was 57.8%, 51.1%, and 27.3% in stage IIIA, IIIB, and IVA, respectively. Disease free survival rate was 57.1%, 39.5%, and 25.0% in each stage at five years. Five year overall survival rate was 66.7%, 51.0%, and 33.3% in stage IIIA, IIIB, and IVA, respectively.

Stage was not statistically significnat in terms of locoregional control, disease free survival, and overall survival.

Number of pregnancies, initial hemoglobin level, obstructive uropathy on IVP, pelvic sidewall invasion on CT, pelvic LN status on CT, and bladder invasion on CT turned out to have prognostic significance.

Patients with four or less pregnancies had poorer locoregional control ($p=0.02$) and disease free survival ($p=0.01$) than patients with five or more pregnancies. Those with initial hemoglobin of less than 10 g% had worse locoregional control ($p=0.03$) and disease free survival ($p=0.04$). A group of patients with obstructive uropathy on IVP had poorer disease free survival ($p=0.04$). Enlargement of pelvic LN on CT affected disease free survival adversely ($p=0.03$). Invasion to pelvic sidewall on CT was associated with poor locoregional control ($p=0.02$), disease free survival ($p=0.01$), and overall survival ($p=0.002$). Patients with bladder invasion on CT had lower overall survival ($p=0.03$) than patients without bladder invasion. Age, ECOG performance status, history of diabetes and hypertension, histology, shape and size of primary tumor, extent of parametrial involvement on physical examination, paraaortic lymph node status on CT, uterine invasion on CT, rectal invasion on CT, neutrophil count, lymphocyte count, and initial level of BUN and creatinine were not significantly related to locoregional control, disease free survival, or overall survival.

Eleven variables selected from the result of univariate analysis were put into multivariate analyses; the five variables found to be significant in univariate analysis (the number of pregnancies was exclueded because of too many missing observations) and six additional factors (stage, age, histology, tumor shape, tumor size, PAN on CT) which have been reported to be significant in some reports[15~17]. Because abdomino-pelvic CT was not done in all patients, we carried out multivariate analysis with 7 variables excluding CT findings in 147 patients and with 11 variables including CT findings in 95 patients.

In multivariate analysis excluding CT findings, none of the variables was significant prognosticator in terms of locoregional control, disease free survival, and overall survival. In contrast, when CT findings were included, pelvic LN status on CT was a significant factor in terms of disease free survival and the tumor size was significant in terms of overall survival (Table 4).

Table 4. Prognostic Factors, Multivariate Analysis (N=95)

Factor	Relative risk		
	LRC	DFS	OS
Stage			
IIIA	1.00	1.00	1.00
IIIB	0.72	1.03	0.60
IVA	0.95	1.22	0.75
Age (year)			
≥50/<50	1.04	1.00	0.81
Hemoglobin (g%)			
<10/10≥	1.38	1.45	1.07
Histology			
non-sq/sq	1.13	1.00	0.89
Tumor shape			
infiltr/non-infiltr	0.70	0.47	0.30
Tumor size (cm)			
≥4/<4	1.76	1.21	2.21**
Obsructive uropathy			
present/absent	1.12	1.09	1.29
CT finding			
Pelvic LN			
enlarged/normal	1.57	1.86**	1.64
PAN			
enlarged/normal	1.01	0.89	1.64*
Sidewall invasion			
positive/negative	1.45	1.49	1.97
Bladder invasion			
positive/negative	1.25	1.29	1.77

*$0.05<p<0.1$
**$p<0.05$

DISCUSSION

Many pretreatment factors have been reported to be associated with survival in patients with carcinoma of the uterine cervix. But most of the studies anlyzed the prognostic factors in early stage cervix cancer or all stage cervix cancer and the possible interactions between some factors frequently made it difficult to interpret the result of those studies. Our analyses provide valuable infor-

mations about prognostic importance of various facotrs in patients with locally advanced cervix cancer treated with radiation therapy alone.

1. Locoregional Control

In univariate analysis of this study, number of pregnancies, pelvic sidewall invasion on CT, and initial hemoglobin level were signicant prognostic factors. The relation of number of pregnancies with locoregional control was previously reported. Kapp et al[16] found that patients with greater than four pregnancies had better locoregional control and disease free survival and this finding was related to the treatment details; lower radium exposures employed in patients with less copious vagina were believed tio be related to a history of fewer pregnancies.

In the evaluation of parametrium, abdominopelvic CT has been known to be less accurate than physical examination[18,19]. But in this study patients with invasion to pelvic sidewall on CT had poor locoregional control and disease free survival. Invasion to pelvic sidewall on CT may indicate more extensive tumor among patients with fixation to pelvic sidewall on physical examination.

Several clinical studies[20~22] suggested adverse effect of low hemoglobin level on local control of tumor treated with radiotherapy. In our study initial hemoglobin level was significantly associated with locoregional control and disease free survival in univariate analysis. This pognostic value was not proven in multivariate analysis. This finding is exactly in accordance with Girinski's study[23]. He reported that hemoglobin concentrations before treatment, before intracavitary application, and during treatment were significant in univariate analysis. In multivariate analysis, however, hemoglobin concentration during treatment only and patients with at least one value below the threshold of 10 g% had a significantly higher risk of locoregional failure. In this study, hemoglobin levels before intracavitary applicaiton and during treatment were not analyzed because high hemoglobin level was maintained after start of treatment by tranfusion as needed. Prognostic significance of hemoglobin level and transfusion should be clarified by further studies.

In multivariate analysis none of factors analyzed was associated with locoregional control. Kapp et al[16], using a Cox model, reported a significant increase in locoregional failure for patients with young age, fewer number of pregnancies, and high neutrophil count. but he analyzed patients with stage IB to IVA and 55% of patients were stage IB or IIA. In our study[24] on all stage cervix cancer clincal stage, histology, size of primary tumor, and pelvic LN status on CT were significant facotrs in multivariate analysis. On the contrary, many pretreatment facotrs known to be significant in cervix cancer were not demonstrated to be significant in this advanced stage group. It seemed that advanced stage itself carries such a poor prognosis that other factors had little significance in terms of locoregional control.

Some authors[1,7,17,25] reported that bilateral pelvic sidewall fixation affected locoregional control adversely compared with unlateral fixation in stage IIIB disease, but this was not proven in this study.

2. Disease Free Survival

In univariate analysis, in addition to the factors that were significant for locoregional control, obstructive uropathy on IVP and pelvic LN status on CT turned out to be significant prognostic factors. Obstructive uropathy on IVP was also marginally significant in terms of locoregional control ($p=0.08$) and overall survival ($p=0.07$), but not significant in multivariate analysis. On the contrary, Girinski et al[23] reported that ureterohydronephrosis on IVP was significantly associated with locoregional control and disease free survival in multivariate analysis as well as in univariate analysis. But they included patients with stage IIB disease that had essentially better prognosis than stage IIIB disease. The significance of hydronephrosis would be less in the patient group of this study, stage IIIA-IVA.

In multivariate analysis, only pelvic LN status on CT was significant. Many surgical series[26~29] demonstrated the prognostic importance of pelvic LN status in early stage cervical cancer. Chung et al[26] reported that patients who had positive nodes had more local recurrences (24% vs. 6%) and distant metastases (28% vs. 0%) and those with grossly positive nodes had more distant metastases (60% vs. 7%) than those with microscopically positive nodes. Martimbeau et al[27] reported that patients with pelvic node metastases below the common iliac group have a much better prognosis than patients in whom metastases are located in the common iliac nodes; in addition, when nodal involvement is below the common iliac level, patients with disease limited to one node or one group of nodes do not have a better prognosis than patient with multiple metastatic nodes. Girinski et

al[23]. reviewed 386 patients with stage IIB or III cervical cancer treated with radiation therapy and found that lymph node status on lymphangiogram significantly affected disease free survival. We confirmed prognostic significance of pelvic LN status on CT despite of limitation of diagnostic sensitivity[19,30]. But further investigations on prognostic importance of size, number, and site of enlarged pelvic LN on CT should be performed.

Several authors[15,31] reported prognostic significance of pathologically positive PAN. In our series, patients with enlargement of PAN on CT had poorer locoregional control, disease free survival, and overall survival. But these differences were not statistically significant. This finding may have resulted from relatively lower incidence of enlargement of PAN compared with the rate of biopsy proven PAN metastasis[19,30,32].

3. Overall Survival

In univariate analysis, extent of parametrial invasion on CT and bladder invasion on CT were significant factors. But their prognostic value disappeared in multivariate analysis controlled for other variables including stage. Instead of them, size of primary tumor which is marginally significant ($p=0.09$) in univariate analysis was the single significant prognostic factor in multivariate analysis. Prognostic significance of tumor size and its correlation with LN metastasis was reported previously by several authors[26,27,33,34]. Most of these studies included only patients with early stage disease treated with radical hysterectomy. In our study[35] on early stage cervix cancer treated with radation therapy tumor size was also significantly associated with overall survival.

Stehman et al[15] reviewed 626 patients who underwent operative assessment of the PAN and treated with radiotherapy. He suggested that PAN status was the most significant prognostic factor in predicting survival in multivariate analysis. Of course, stage, age, tumor size, pelvic node status, performance status, and extent of parametrial involvement were also significant. Podczaski et al[31] reported that tumor histology, PAN status, tumor size, and presence of intraperitoneal disease were significant prognostic factors in patients who underwent selective paraaortic lymphadenectomy and exploratory laparotomy prior to initiation of radiotherpy. As mentioned previously, low sensitivity of CT in detecting PAN metastasis might have obscured the prognostic importance of PAN status in survival in our study.

CONCLUSION

Multivariate analyses of prognostic factors in stage III and IVA uterine cervix treated with radiotherapy showed that none of analyzed factors was associated with locoregional control and only pelvic LN status on CT affected the disease free survival and size of primary tumor was the single significant factor in terms of overall survival. It is believed that advanced stage itself carries such a poor prognosis that relatively few a factors are significant prognosticators in contrast to early stage cervix cancer. It is suggested that CT findings are useful in predicting prognosis and determining treatment policy although more investigations are needed to identify its prognostic significance as well as its diagnostic accuracy.

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= 국문초록 =

국소진행된 자궁경부암에 있어서의 예후인자 분석

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국소진행된 자궁경부암에 있어서의 예후인자를 알아보기 위하여 1979년 3월부터 1986년 12월까지 서울대학교병원에서 근치적방사선치료를 시행받은 154명의 환자를 대상으로 후향적 분석을 시행하였다.

FIGO 병기 IIIA, IIIB, IVA의 환자 수는 각각 8, 134, 12명이었고 병기에 따른 5년 국소치료율은 각각 58%, 51%, 27%이었으며 5년 무병생존율은 각각 57%, 40%, 25%, 5년 생존율은 각각 67%, 51%, 33%이었다.

단변수분석에 의하면 임신 횟수, 혈색소치, 전산화단층촬영상 골반측벽 침범소견이 국소치료율에 영향을 미치는 인자 이었고 임신 횟수, 혈색소치, 전산화단층촬영상의 골반측벽 침범소견과 함께 요로조영술상의 요로폐쇄증, 전산화단층촬영상의 골반임파절 비대가 무병생존율에 영향을 미치는 인자이었으며 생존율에 영향을 미치는 인자는 전산화단층촬영상의 골반측벽 침범소견 및 방광침범소견이었다.

다변량분석에 의하면 국소치료율에 영향을 미치는 인자는 없었고 무병생존율에 영향을 미치는 인자는 전산화단층촬영상의 골반임파절 비대이었으며 생존율에 영향을 미치는 인자는 원발병소의 크기였다.