

The Results of Radiation Therapy Alone vs Radiation Plus Chemotherapy of Uterine Cervix Cancer

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Abstract=

Purpose : Radiation therapy(RT) is conventionally standard treatment for locally advanced stage for uterine cervix cancer. Recently to improve treatment results, combined chemotherapy and radiation therapy was tried. We retrospectively analysed our experience of 122 patients.

Comparison of the results in 45 patients treated with RT alone and 77 patients treated with RT plus chemotherapy was made

Materials and Methods : From January 1985 to December 1991, 122 patients with cervix cancer were treated with whole pelvic external RT and ICR(34 1 ICR, 77 2 ICR, 11 high dose rate ICR) in our department. Forty five patients were treated with RT alone, and 77 patients were treated with combined RT plus chemotherapy. Mean age was 58 years(range:29-81). Histologic types were 111 squamous cell carcinoma, 5 large cell carcinoma, 3 adenocarcinoma, and 2 adenosquamous cell carcinoma. According to the FIGO stage 6 had stage IA(4.9%), 11 had IIA(9.0%), 37 had IIB(30.3%), 3 had IIIA(2.5%), 63 had IIIB(51.6%), and 2 had stage IV(1.6%). In 77 patients with RT plus chemotherapy, 36 patients were treated with VBP(vinblastin, bleomycin, cisplatinum) , 39 patients with cisplatinum plus 5-FU and 2 patients with 5-FU .

Results : Complete response after external RT (3960cGy-5500cGy) was achieved in 61 patients(50%). The actuarial 5 year and 9 year survival rate was 57.8% and 53.9%, respectively. Five year actuarial survival rate was 63.1% with RT alone(n=45) and 55.9 % with RT plus chemotherapy(n=77).

The 5 year survival rate was 35.5% for 1 course of ICR and 67% for 2 courses of ICR. There was statistically significant advantage of survival with RT alone group who were treated with 2 courses of ICR and dose to the A point>=8000cGy (4/25 died). In RT plus chemotherapy group, dose response was not seen and there was no difference in 5 year survival between 1 course and 2 course of ICR (50% vs 56.8%), and dose to point A less than 8000 cGy and more than 8000 cGy(55.6% vs 55.7%). There was no significant difference in survival between RT alone and RT plus chemotherapy for patients with tumor size greater than 3cm in size.

Five year survival rate for early stage (Stage IB and IIA) with RT alone group and with RT plus chemotherapy group was 60 % and 77.0 %, respectively. In advanced stage (stage IIB, IIIA, IIIB, IVA) the 5 year actuarial survival rate were 62.6%, for RT alone group vs 53.6% for RT plus chemotherapy group.

Conclusion : Present study demonstrates that there is no survival advantage with adding chemotherapy in advanced stage of uterine cervix cancer. RT alone is considered as treatment of choice for patients with locally advanced cervix cancer. There was increased survival in RT alone group treated with RT dose above 8000 cGy to point A and 2 course of ICR, but 2 course of ICR and RT dose above 8000 cGy to point A did not affect survival advantage in RT plus chemotherapy group

Key Words : Cervix cancer, Chemoradiotherapy, Radiation therapy, Intracavitary radiation

INTRODUCTION

Definitive pelvic radiation therapy has been shown to be effective in treating patients with carcinoma of the cervix with locally advanced disease. Despite improvement in radiation equipment and technique, cervix cancer has appreciable local and distant failure rates.

Approximately two thirds of patients with locally advanced disease have local failure in the pelvis¹⁾. To improve local control and to reduce distant metastasis combined RT plus chemotherapy therapy has been investigated to overcome this limitation. Chemotherapy and radiation therapy theoretically interact by sensitization of tumor for local disease and systemic chemotherapy for subclinical metastasis^{2, 3)}.

This study analyzed the any potential survival benefit of combined RT plus chemotherapy for cervix cancer, and appropriate radiation doses for radiation alone or RT plus chemotherapy patients.

MATERIALS AND METHODS

From January 1985 to December 1991, 122 patients with carcinoma of the cervix treated with external radiation therapy alone or combined RT plus chemotherapy followed by intracavitary radiation in our department were evaluated retrospec-

tively.

Patients had follow-up range from 5 to 117 months (median 60 months) for alive patients and from 3 to 67 months (median 36 months) for dead patients. Forty five patients were treated with RT alone, and 77 patients were treated with combined RT plus chemotherapy. Mean age was 58 years (range 29-81 years). According to the FIGO stage 6 had stage IB(4.9%), 11 had IIA(9.0%), 37 had IIB(30.3%), 3 had IIIA(2.5%), 63 had IIIB(51.6%), 2 had stage IV(1.6%). The pathological classification revealed 111(90.6%) squamous cell carcinoma, 4 adenocarcinoma, 2 adenosquamous cell carcinoma, and 2 large cell carcinoma. In view of the tumor size, 19 were smaller than 3 cm, 39 were 3-5cm, and 39 were larger than 5cm. The characteristic of each group was shown in Table 1.

1. Irradiation Techniques

External beam radiation was delivered by Co⁶⁰ or 10 MV linear accelerator. Patients were treated with external beam RT followed by 1 or 2 course of intracavitary radiation(ICR). External radiation dose ranged from 3960 cGy to 5500 cGy. After 4000 cGy, median midline shield with 4cm block was done routinely and midline shield was not used to the patients who were scheduled to have only 1 course of ICR. External beam radiation was administered through AP and PA portals. Daily fractionation was 180 cGy to 200 cGy

Table 1. Patient Characteristics of Cervix Cancer

	RT alone	RT+chemo	Total
No of patients	45	77	122
Follow-up period			
median(mo)	60	60	60
range(mo)	11-106	5-117	5-117
Age mean(yr)	61	56	58
range	32-87	29-73	29-87
stage			
I B	3	3	6
II A	4	7	11
II B	18	19	37
III A	1	2	3
III B	18	45	63
IV A	1	1	2
Histology			
squamous	41	70	111
adenoca	1	3	4
adenosquamous	0	2	2
large cell	3	2	5
Tumor size			
unknown	17	8	25
<3	10	9	19
3-5cm	9	30	39
>=5cm	9	30	39

Table 2. Radiation Treatment Methods of Cervix Cancer

	RT alone	RT+chemo	Total
Ext RT dose (cGy)			
mean	4977	5073	5038
range	4000-6000	3200-6500	3960-5500
ICR(No.)			
1	14	20	34
2	29	48	77
high dose rate	2	9	11
A point dose (cGy)			
mean	8040	8020	8027
range	7500-8900	6500-8900	6500-8900
<8000	20	24	44
>=8000	25	53	78

tumor dose, five times per week.

2. Brachytherapy

Until 1987, TAO applicator(Japan) was used and total of 20 patients were treated by TAO applicator. Since then FSD applicator(U.S.A.) has been used and 89 patients were treated by FSD applicator. Eleven patients were treated with high dose rate brachytherapy during transient period at outside hospital.

Point A and B point dose was prescribed by computer calculation. First ICR was performed 1-2 weeks after the completion of external beam irradiation and 2nd ICR was done with 1-2 weeks interval following 1st ICR. Planned dose to point A was 8000-8500 cGy. Actual prescription dose to the point A varied from 6500-8900 cGy. Thirty five patients received 1 course of ICR, 77 patients received 2 course of ICR and 11 had high dose rate brachytherapy. Radiation treatment methods

Table 3. Type of Chemotherapy of Cervix Cancer

	No of patients
VBP(1-8 cycle)	36
1-2 cycle	11
>=3 cycle	25
chsplatinum(1-7 cycle)	39
1-2 cycle	5
>=3 cycle	34

Table 4. Comparison of Treatment Results of Two Groups(%)

	5 yr survival	RT alone	RT+chemo	Total
Tumor size				
<3CM		66.6	77.8	73.6
>=3CM		48.9	48.7	48.8
#of ICR				
1 ICR	18.6		50	35.5
2 ICR	82.8		56.8	67
HDR ICR	50		67	58
A point dese(cGy)				
<8000	27.2		55.6	36.5
>=8000	91.4		55.7	67

have been summerized in Table 2.

3. Chemotherapy

Of 77 chemotherapy combined patients, 36 patients were treated with VBP(vinblastin, bleomycin and cisplatinum) as a neoadjuvant therapy. Vinblastin 4mg/M² bleomycin 16mg/M² and cisplatinum 50mg/M² were injected at day 1 and bleomycin was injected at day 2. After 3 cycles of chemotherapy patients who had good response underwent radical operation. But patients who did not finish planned dose of chemotherapy or who had poor response were referred for curative radiation. Thirty nine patients received cisplatinum plus 5 FU, and 2 patients who had poor renal funtion had received 5-FU alone as concomittant therapy. Cisplatinum 1mg/kg were injected for 3 day and 500 mg of 5 FU were infused for 5 days every 3 weeks. The type and schedule of chemotherapy were shown at Table 3

Analysis of actuarial survival was made by Kaplan Meyer method and comparison between groups was made using log-rank test.

RESULTS

Complete response after external RT was observed in 50%(55.5% for RT alone vs 46.7% for RT plus chemotherapy). The actuarial 5 year survival rate was 57.8% for entire group of patients. The 5 year actuarial survival rates for RT alone patients and for RT plus chemotherapy were 63.1 % and 55.8%, respectively, and that was not statistically significant(p>0.05)(Fig. 1). The 5 year survival rates for 1 course of ICR, 2 course of ICR and high dose ICR were 35.5%, 67% and 58%, respectively. Patients treated with 1 ICR were noted to have poor survival. There was statistically significant advantage of survival with RT alone group who were treated with 2 course of ICR (18.6% for 1 ICR vs 82.8% for 2 ICR) and dose to the A point>=8000 cGy (27.2% for <8000 cGy vs 91.4% for >=8000 cGy). However for the patients with RT plus chemotherapy group, there was no significant difference in 5 year survival rate between 1 course and 2 course of ICR (50% vs 56.8%), and A point dose less than 8000 cGy and more than 8000 cGy(55.6% vs 55.7%).

Tumor size less than 3cm showed better survival than those of larger ones (74.6% vs 48.8%). Average tumor sizes of RT alone group and RT plus chemotherapy group were 3.6cm and 4.4cm, respectively. Tumor size was larger in RT plus chemotherapy group than in radiation alone group. However among patients with tumor size larger than 3cm, average tumor sizes in RT alone and RT plus chemotherapy group were the same (4.8cm vs 4.9cm). There was no difference in survival between RT alone and RT plus chemotherapy groups with tumor size larger than 3cm (48.8% vs 48.7%). The difference of 5 year survival with two groups by tumor size, number of ICR and A point dose was shown at Table 4.

The 5 year survival rate of early stage(stage IB and IIA) for 7 patients who was treated with RT alone was 60% in contrast to 77.8% for 10 patients with RT plus chemotherapy therapy. But the

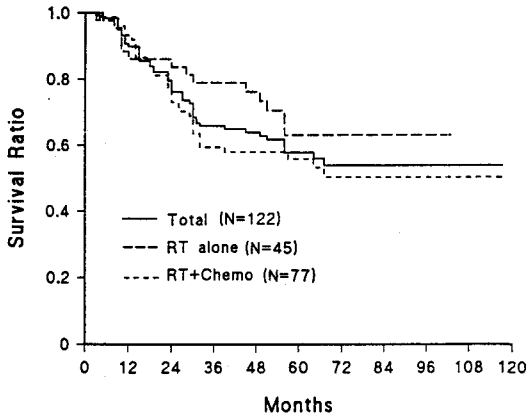


Fig. 1. Actuarial survival of patients.

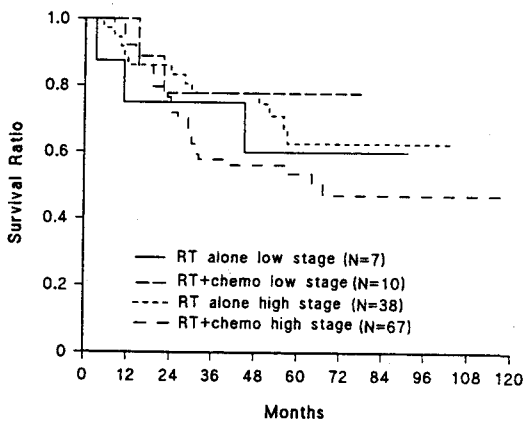


Fig. 2. Comparison of survival of RT or RT+chemo patients by stage.

number' of patients was too small to make any comparison in early stage disease(Fig. 2). In advanced stage(stagelIIB, IIIA, IIIB, IVA) the 3, 5 year and 9 year actuarial survival rates were 77.9%, 62.6% and 62.6% for RT group vs 57.8%, 53.6% and 53.6% for RT plus chemotherapy group, respectively. Slightly better survival with RT group was noted, but that was not statistically significant(Fig. 2).

Slightly increased survival of RT plus chemotherapy patients was noted at 1 year(93.2% vs 86%) but a large number of death occurred between 18-30 months and late death after 5 years was seen in RT plus chemotherapy group. On the contrary no patients died after 5 years in RT

alone group(Fig. 1).

DISCUSSION

There are several rationale for using combined chemotherapy. The goals are reduction of the primary tumor size before initiating radiation therapy and eradication of micrometastasis. In a small pilot study of Gynecologic Oncology Group, only 1 of 11 patients with stage IIIB or IV disease were alive after 25 months with ciplatinum chemotherapy⁴. Symonds et al reported the use of cisplatin, bleomycin, and vincristin for two cycles before radition therapy in stage III or IVA disease with 66% actuarial survival at 30 months⁵. Sardi et al used the same agents reported promising results for stage IIB and IIIB disease⁶. However others noted no complete response and a significant incidence of progression of disease during chemotherapy⁷. The combination of cisplatin, bleomycin, and mitomycin, and vincristine was associated high response rate but only 23% of patients remained disease free after radiation therapy⁸. Although most phase II results seemed promising with chemotherapy, none of phase III studies have shown significant benefit⁹⁻¹¹.

The aim of concomittant chemotherapy is to interact synergistically with radiation therapy in addition to the reduction of tumor size and eradication of micrometastasis^{2, 3}. Chemotherapy might decrease the shoulder or increase the slope of radiation dose response¹². Hydroxyurea, cisplatin and 5-FU were commonly used and some have reported increased survival of patients with advanced cancer¹³⁻¹⁷. However, others reported no advantage with cisplatin and 5-FU in randomized study¹⁸.

In this study concomittant chemotherapy with cisplatinum plus 5-FU resulted in slightly better 5 year survival than neoadjuvant chemotherapy with VBP but there was no statistical significance. There was no benefit of RT plus chemotherapy group in advanced stage cervical cancer(stage IIB, IIIA-B, IVA). The actuarial survival at 5 years for

radiation alone group was slightly better than RT plus chemotherapy group (62.6% vs 53.6%) although that was not statistically significant in advanced stages.

No survival advantage of RT plus chemotherapy group was probably due to the different size of tumor at initial presentation even though the stage was same. Average tumor size was 3.6cm for RT alone group and 4.4 cm for RT plus chemotherapy group. Perez reported high pelvic failure with tumor size larger than 3cm in stage IB, IIA, IIB disease¹⁹. Others reported tumor size more than 5 cm or 6cm in diameter was found to be an important prognostic factor for survival²⁰⁻²⁴. Our data showed significantly better prognosis for tumor less than 3 cm in size. The reason for those patients treated with chemotherapy having decreased survival is that chemotherapy group has more patients with large tumor size (78% vs 40%, tumor size ≥ 3 cm). Combined treatment was designed to overcome poor prognosis of large size of tumor with synergistic effect with radiation or preradiation chemotherapy. Among patients with tumor size larger than 3cm, same survival of radiation group and chemoradiation group was seen. This study failed to demonstrate any advantage in adding chemotherapy in large tumor size. Previous report from our department demonstrated 5 year survival was 56.7% for stage IIB and 60.6% for stage III. At that time we did not give any chemotherapy and study population included bulky and non bulky size of tumor²⁵. The five year survival was same as this result (58.7% vs 58.1%).

Dose-response relationship of radiation therapy for cervix cancer is clear. Increased doses of radiation results in increased rates of local control. This study showed increased survival with A point dose ≥ 8000 and 2 ICR. Eleven patients who were treated with high dose rate ICR had the same survival as those with 2 course of ICR. In RT alone group 2 course of ICR and A point dose over 8000 cGy is very important. On the contrary, patient who were treated with RT plus chemotherapy did not show any survival advantage

with 2 course of ICR or A point dose over 8000 cGy. Chemotherapy has known to have the synergistic effect with radiation. The result of no advantage of chemotherapy is probably due to the same target of radiation and chemotherapy, and chemotherapy would act only as adding radiation dose to the tumor cells. Generally as tumor volume increases greater RT doses are required. However tumor dose response is usually sigmoid shape and maximal tumor response is different from each tumor cells and delivering radiation doses seemed to be limited due to surrounding normal tissue²⁶⁻²⁸. We tried to limit rectal and bladder dose in the range of 6500-7000 cGy and no patients was reported as death due to treatment related complications.

There was no difference in survival with A point dose between 8000-8500 cGy and more than 8500 cGy in RT alone patients. Maximal tumor dose response of our patients would be 8000-8500 cGy for RT alone and 7500-8000 cGy for RT plus chemotherapy group.

CONCLUSION

1) There was slightly better survival in RT alone compared to RT plus chemotherapy.

2) Use of 2 course of ICR with RT dose above 8000 c Gy to point A is very important treatment factor for RT alone group. However, when combination RT plus chemotherapy was planned, the number of ICR and dose to A point did not affect prognosis. Those results suggest that dose reduction is possible when the patients are treated with combined RT plus chemotherapy.

3) Patients with tumor size larger than 3cm did not show any survival advantage with addition of chemotherapy to radiation. Since there was no benefit of these types of chemotherapy on the survival in bulky tumor, optimal schedule and agents are needed for better results.

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국문초록=

자궁경부암에서 방사선 단독요법 및 항암화학과 방사선 병용요법의 치료성적

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목적 : 국소적으로 진행된 자궁경부암의 치료는 방사선 단독요법이 주 치료였으나 근래에는 좀 더 완치율을 높이기위해 약물치료와 병행하여 방사선치료가 시행되고 있다. 저자들은 45명의 방사선 단독요법과 77명의 항암화학과 방사선의 병용요법의 치료성적을 후향적으로 분석하였다.

방법 : 1985년 1월부터 1991년 12월까지 한양대학병원 치료방사선과에서 외부방사선 및 강내방사선치료를 받은환자 122명을 대상으로 후향적으로 분석하였다. 34명은 ICR 1회, 77명은 ICR 2회, 11명은 고선량 강내근접 방사선치료를 받았다. 연령분포는 29세부터 81세였고, 중앙연령은 58세였다. 추적기간은 5개월에서 117개월(5명이 34개월 미만)로 중앙값은 60개월이었다. 조직병리상 111명이 squamous cell ca, 5명이 large cell ca, 4명이 adenoca, 2명이 adenosquamous cell ca였다. FIGO 병기로 IB 6명(4.9%), IIA 11명(9.0%), IIB 37명(30.3%), IIIA 3명(2.5%), IIIB 63명(51.6%), IVA 2명(1.6%)이었다. 항암화학요법을 병용한 환자 77명중 36명은 VBP, 39명은 cisplatin 과 5-FU, 2명은 5-FU 제제로 치료받았다.

결과 : 외부방사선조사량 3960 cGy에서 5500 cGy를 받은환자에서 61명(50%)이 육안적으로 완전관해를보였다. 5년 및 9년 생존율은 전체환자에서 각각 57.8%, 53.9%였고 방사선 단독요법의 5년 생존율이 63.1%, 방사선과 항암화학복합요법의 5년 생존율은 55.9%였다. 항암제 VBP(vinblastin, bleomycin, cisplatinum)로 치료받은 환자에서 5년 생존율이 63%이고 cisplatin으로 치료받은 환자는 50%이나 통계적인 유의성은 없었다.

ICR 회수에따른 5년 생존율은 1회 ICR에서 36.5%, 2회 ICR에서 67%였다. 방사선단독요법으로 치료받은 환자중 A point에 8000 cGy이상 받은 환자에서 5년 생존율이 91.4%이었고 8000 cGy 미만 환자는 27.2%로 통계적으로 유의한 생존율의 향상을 보였다($p < 0.01$). 항암화학요법으로 치료받은 환자는 A point의 dose에 따른 생존율의 차이를 보이지 않았으며(< 8000 cGy 55.6% vs ≥ 8000 cGy 55.7%) 1회의 ICR 과 2회의 ICR의 5년 생존율에도 큰 차이가 없었다(50% vs 56.8%). 병변크기가 3cm 이상인 환자에서 방사선 단독치료법과 항암화학치료법과의 5년 생존율의 차이가 없었다(48.9% vs 48.7%).

초기 병변에서 항암화학치료를 받지않은 군과 받은 군의 5년 생존율은 60%와 78%이나 숫자가 매우적어 의미가 없었고 진행된병기에서 5년 생존율은 방사선 단독군이 조금 좋았으나 통계적 유의성은 없었다(62.6% vs 53.6%) ($p > 0.05$).

결론 : 본 연구결과 방사선치료를 항암화학 병용은 생존율향상을 시키지 못하였다. 방사선단독요법이 국소적으로 진행된 환자에 치료방법이며 A point에 8000 cGy이상 받은환자에서 생존율이 높았고 항암화학 병용요법 치료에서는 A point의 방사선양이 생존율에 영향을 미치지 않았다.