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Treatment of Carcinoma of the Uterine Cervix with High-Dose-Rate Intracavitary Irradiation using Ralstron

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From May 1979 through December 1981 a total of 524 patients with carcinoma of the uterine cervix were treated by radiation therapy with curative intent. Among the 524 patients, 356 were treated with a high-dose-rate (HDR), remote-controlled, afterloading intracavitary irradiation (ICR) system using a cobalt source (Ralstron), and 168 patients received a low-dose-rate (LDR) ICR using a radium source. External beam irradiation with a total dose of 40- 50 Gy to the whole pelvis followed by intracavitary irradiation with a total dose of 30-39 Gy in 10-13 fractions to point A was the treatment protocol. ICR was given three times a week with a dose of 3 Gy per fraction. Five-year actuarial survival rates in the HDR-ICR group were 77.6% in stage IB (N=20), 68.2% in stage II (N=182), and 50.9% in stage III (N=148). In LDR-ICR group, 5-year survival rates were 87.5% in stage IB (N=22), 66.3% in stage II (N=91), and 55.4% in stage III (N=52). Survival rates showed a statistically significant difference by stage, but there was no significant difference between the two ICR groups. Late bowel complications after radiotherapy were noted in 3.7% of the HDR-ICR group and 8.4% of the LDR-ICR group. There was no severe complication requiring surgical management. The incidence of bladder complications was 1.4% in the HDR-ICR group and 2.4% in the LDR-ICR group. The application of HDR-ICR was technically simple and easily performed on an outpatient basis without anesthesia, and the patients tolerated it very well. Radiation exposure to personnel was virtually nil in contrast to that of LDR-ICR. Within a given period of time, more patients can be treated with HDR-ICR because of the short treatment time. Therefore, the HDR-ICR system is highly recommended for a cancer center, particularly one with a large number of patients to be treated. In order to achieve an improved outcome, however, the optimum dose-fractionation schedule of HDR-ICR and optimum combination of intracavitary irradiation with external beam irradiation should be determined through an extensive protocol study with different treatment regimens.

Key Words: Carcinoma of the uterine cervix, High-dose-rate irradiation, Intracavitary irradiation, Remotely controlled afterloading system.

INTRODUCTION

The high-dose-rate intracavitary radiation (ICR) system has several advantages compared with the low-dose-rate ICR system, namely short treatment time, less radiation exposure to medical personnel, no major anatomy changes during treatment, no overnight nursing, reduced packing needs, possible optimization of the treatment plan, and treatment can be performed on an outpatient basis[1,2]. So, the high-dose-rate ICR system is gaining increasing popularity worldwide. In Korea, carcinoma of the uterine cervix is the most common female cancer and constitutes 20-30% of all female cancers with an annual incidence rate of 24.2per 100,000 female population[3,4]. Annually more than 200 patients with uterine cervical cancer are referred to our Department of Radiation Oncology, Yonsei University Hospital. Because of the large number of patients with cancer of the cervix, there was a need to introduce a high-dose-rate ICR system, and Ralstron (remotely controlled afterloading system using high-dose-rate Co-60) was first installed in 1979. Since then, about 2,000 patients have been treated with this system.

We retrospectively analyzed the treatment results of 354 patients who received high-dose-rate ICR during the first three years to assess the useful-

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ness of this system and validity of our protocol.

MATERIALS AND METHODS

From January 1979 to December 1981, 630 patients with uterine cervical cancer were registered in our department (Table 1). Among them, 106 patients were treated with external beam irradiation alone due to reasons such as postoperative status in 90 cases postoperative recurrence in 5 cases, stump carcinoma in 4 cases, and stage IVB in 2 cases. Five hundred twenty-four patients received external beam irradiation combined with intracavitary irradiation. Among them, 356 patients were treated with high-dose-rate ICR (HDR-ICR) and 168 patients were treated with conventional low-dose-rate ICR (LDR-ICR). The latter group was composed of cases who were referred for external irradiation from an affiliated hospital where intracavitary irradiation was performed with a Henschke applicator with a radium source. We analyzed treatment results of 356 cases of the HDR-ICR group and compared them with those of the LDR-ICR group. All cases were previously untreated, histologically proven carcinoma of the uterine cervix with an intact uterus. Patients were staged according to the system of the International Federation of Gynecology and Obstetrics (FIGO). FIGO stage IA & IVB cases were excluded from this analysis.

1. Patients Characteristics

Clinical characteristics of patients are listed in Table 2. The most prevalent age was the sixth decade followed by the fifth and seventh decades. Squamous cell carcinoma was 92.9% and adenocarcinoma was 4.1%. This study was a non-

Table 1. Treatment Modalities in Uterine Cervical Cancer (1979–1981, YCC)

Treatment modality	No. of patients	
ERT* + ICR		524
High–Dose–Rate ICR	356	
Low–Dose–Rate ICR	168	
ERT alone		106
Post-op.	90	
Post-op recurrence	5	
Stump Ca.	4	
Incomplete RT	5	
Palliative RT (Stage IVB)	2	
Total		630

* ERT : External Radiotherapy

Table 2. Patient Characteristics

	High Dose Rate ICR No. of pts. (%)	Low Dose Rate ICR No. of pts. (%)
Age (years)		
⩽ 29	5 (1.4)	4 (2.4)
30 – 39	34 (9.6)	18 (10.9)
40 – 49	99 (28.0)	45 (27.3)
50 – 59	160 (45.2)	74 (44.8)
60 ⩽	56 (15.8)	24 (14.6)
Pathology		
SCC	329 (92.9)	152 (92.1)
LCNK	151	25
LCK	31	2
Small cell	10	2
Not specified	137	123
Adenoca.	14 (4.1)	7 (4.3)
Others	11 (3.0)	6 (3.6)
Size of tumor		
< 3 cm	97 (27.4)	60 (36.4)
3 – 6 cm	190 (53.7)	89 (53.9)
6 <	67 (18.9)	16 (9.7)
Shape of tumor		
Exophytic	184 (52.0)	83 (50.3)
Infiltrative	170 (48.0)	82 (49.7)
Endocervical extension		
Not prominent	328 (92.7)	158 (95.8)
Bulky	26 (7.3)	7 (4.2)

SCC=squamous cell carcinoma, LCNK=large cell, non-keratinizing, LCK=large cell, keratinizing.

Table 3. Distribution of Stage

Stage	HDR–ICR No. of pts.(%)	LDR–ICR No. of pts.(%)	Total
IB	20 (5.7)	22 (13.3)	42 (8.1)
IIA	17 (4.8)	34 (20.6)	51 (9.8)
IIB	165 (46.6)	57 (34.6)	222 (42.8)
IIIA	4 (1.1)	0 (0)	4 (0.8)
IIIB	144 (40.7)	52 (32.5)	196 (37.7)
IVA	4 (1.1)	0 (0)	4 (0.8)
Total	354 (100.0)	165 (100.0)	519 (100.0)

randomized retrospective study, but age, pathologic subtype, shape of tumor, and extent of endocervical involvement were equally distributed between the two groups. Difference was only noted in the size of the tumor, with a greater percentage of large tumors was distributed in the HDR-ICR group. Most cases were stage II or III; 42.8% were stage IIB 37.7% were stage IIIB and stage IB was 8.1% (Table 3).

2. Treatment Methods

External pelvic irradiation was performed with a 10 MeV linear accelerator X-ray or Co-60 teletherapy unit. HDR-ICR was performed with a Co-60 remotely controlled afterloading system (Ralstron, manufactured by Toshiba, Japan), and LDR-ICR was performed with a Henschke applicator using radium sources. Ralstron has three sets of Co-60 sources, 3 Ci in tandem and 2 Ci in each ovoid. The tandem source can be moved to five different points to get planned isodose curves for individualized treatment. Port combination was usually 4 field box technique and AP/PA parallel opposed ports when using a midline shield. The volume of external irradiation included internal and external iliac nodes and common iliac nodes to the upper level of the L5 vertebral body.

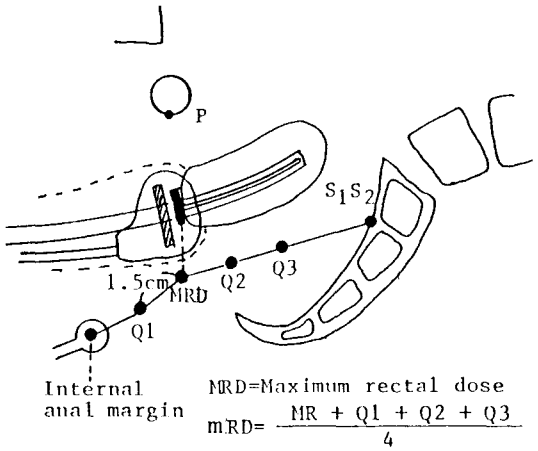

Fig. 1. Schematic representation of the reference points for the maximum rectal dose (MRD) and mean rectal dose (mRD). MRD is 5 mm beneath the posterior vaginal wall and mRD is the average of 4 selected points on the anterior rectal wall. The point QI is 1.5 cm below MRD on the line joining the internal anal margin. Q2 and Q3 are located on the line joining MRD and S1-S2 and lie respectively at 1.5 and 3 cm above MRD.

In the study period, radiotherapy protocol for the uterine cervical cancer mainly depended upon the stage. Intracavitary irradiation was usually performed after 20 to 30 Gy of external pelvic irradiation. After completion of ICR, external irradiation was continued with a midline shield until 40-50 Gy. The dose of whole pelvic irrdiation and ICR was altered according to the stage. ICR dose in an early lesion was greater than in an advanced lesion, 39 Gy on point A in stage I & II and 30 Gy in stage III. Instead of a higher dose of ICR, an earlier midline shield was done at the level of 20 Gy during external irradiation in the early stage. In HDR-ICR the dose per fraction was 3 Gy on point A, three treatments per week (Monday, wednesday, Friday) and the total dose was 30 to 39 Gy over 3 to 4 weeks. The treatment could easily be done on an outpatient basis without anesthesia, and the time required for each treatment was approximately 10 -15 minutes.

LDR-ICR was performed at our affiliated hospital*, where a Henschke applicator loaded with 50-80 mg of a radium source (0.5 mm Pt filter, 15 mm active length) was used. A total of 5140 mg-hr (mean value) was delivered in a single application. The mean dose delivered to point A and point B was 4133.5 cGy and 1625.3 cGy respectively.

3. Dosimetry

After insertion of the tandem and ovoids, orthogonal A-P and lateral films were taken with dummy sources. The bladder neck was identified by Foley catheter balloon filled with 7cc of Hypaque and the rectum was filled with barium. Weighting of the sources was decided by several model plans according to the length of the tandem and distance between the two ovoids. We did not measure rectal doses during ICR individually, but rectal doses were retrospectively calculated by RTP computer for a study of the correlation between complications and rectal doses. Reference points for mobile points of the rectum and bladder were conformed to ICR 38 recommendations. Maximum rectal dose (MRD) was 5 mm beneath the posterior vaginal wall, and mean rectal dose (mRD) was the average of 4 selected points on the anterior rectal wall as indicated in Fig. 1.

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4. Follow-up and Statistical Analysis

The patients were followed up every three months during the first two years and every six months thereafter. In the cases lost to follow-up even by telephone calls to patients' relatives, we could confirm their vital status from the family registration in their hometowns. Four hundred sixty patients among 524 patients were followed for more than five years or until death. Survival rates were calculated by the Kaplan-Meier method, and prognostic factors were evaluated with univariate analysis and multivariate analysis using BMDP2L Cox models. We analyzed the relationship between rectal dose and development of complications. The relationship between rectal dose and application pattern of ICR, such as displacement of ovoid sources from tandem and deviation of the tandem was also analyzed (Fig. 2). This correlation was tested by Pearson correlation coefficients.

RESULTS

1. Initial Response Rates and Survival Rates

Initial response to radiotherapy was assessed at three months after completion of radiotherapy (Table 4). Complete response (CR) rates were not significantly different between the two groups. The CR rate in the HDR-ICR group was 77% and 80% in the LDR-ICR group. Five-year actuarial survival rates in the HDR-ICR group were 77.6% in stage IB, 68.2% in stage II, and 50.9% in stage III. In the LDR-ICR group, 5-year actuarial survival rates were 87.5% in stage IB, 66.3% in stage II, and 55.4% in stage III (Fig. 1). Survival rates showed a statistically significant difference by stage ($p=0.006$ by Mantel-Cox test in HDR-ICR group, $p=0.015$ in LDR-ICR group), but there was no significant differ-

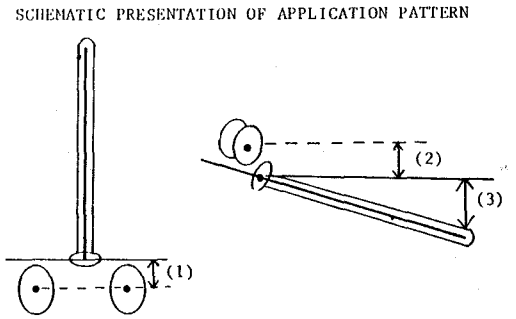

Fig. 2. Schematic presentation of application pattern and check points of Ralstron.
(1) Displacement of ovoid sources from tandem (Y-axis)
(2) Displacement of ovoid sources from tandem (Z-axis)
(3) Deviation of tandem (Z-axis)

Table 4. Initial Complete Response Rate After Radiotherapy

Stage	HDR–ICR	LDR–ICR
	No. of CR / Total No. (%)	No. of CR / Total No. (%)
IB	20/ 20 (100.0)	22/22 (100.0)
IIA	14/ 17 (82.4)	30/34 (88.0)
IIB	145/165 (82.9)	50/57 (87.7)
IIIA	4/ 4 (100.0)	0/ 0
IIIB	91/144 (63.2)	30/52 (57.7)
IVA	1/ 4 (25.0)	0/ 0
Total	275/354 (77.7)	132/165 (80.0)

Table 5. Univariate Analysis of Prognostic Factors in the Patients Treated with High-Dose-Rate ICR

Variables	No. of patients	5 yr survival rate (%)	p-value*
Age (year)			
⩽ 39	39	62.4	
40 – 59	259	61.4	>0.1
60 ⩽	56	60.9	
Pathologic subtype			
squamous cell carcinoma	329	61.4	>0.1
adenocarcinoma	14	57.9	
Size of tumor			
< 3 cm	97	77.3	
3 – 6 cm	190	63.9	<0.005
6 < cm	67	30.1	
Shape of tumor			
exophytic	184	60.9	>0.1
infiltrative	170	61.9	
Endocervical extension			
not prominent	328	63.2	<0.005
bulky	26	38.7	
Initial response			
CR group	275	75.7	<0.005
Non-CR group	79	9.5	

* P-value by log-rank test

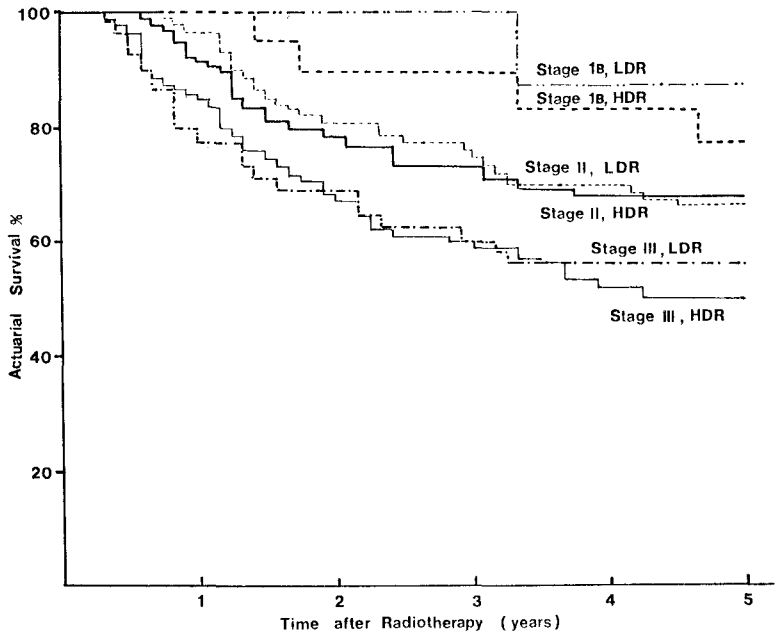

Fig. 3. Actuarial 5 year survival Rates by stage and ICR mode.

ence between the two ICR groups.

2. Prognostic Factors

Several prognostic factors affecting survival were analyzed in the patient group treated with HDR-ICR. For the univariate analysis, patients were categorized by initial clinical manifestations, such as age, pathologic subtype, size of tumor, shape of tumor, endocervical extension, and initial response to radiotherapy, and survival rates according to each factor were analyzed by log-rank test (Table 5). Significant factors were size of tumor, endocervical extension, and initial response to radiation. In the multivariated analysis using BMDP-2L Cox models, age, pathologic subtype, size of the tumor, shape of the tumor, endocervical extension, and initial response were entered and significant factors were initial response ($p=0.001$), size of the tumor ($p=0.039$), shape of the tumor ($p=0.074$), and endocervical extension ($p=0.083$). Age and pathological subtype, squamous cell carcinoma or adenocarcinoma did not affect the survival.

3. Late Complications and Rectal Doses

Late bowel complications after radiotherapy were noted in 3.7% of the HDR-ICR group and 8.4% of the LDR-ICR group. There were no severe complications requiring surgical management. The incidence of bladder complications was 1.4% in the HDR-ICR group and 2.4% in the LDR-ICR group (Table 6). In the HDR-ICR group, there were no significant differences between the recal doses of patients with complications and those without complications (Table 7). Because we had done an early midline shield at the level of 20-30 Gy, mean values of the midline external radiation dose in patients without complication (Group I) and with complications (Group II) were 2489 cGy and 2189 cGy, respectively. Summation of the external irradiation dose to midline and maximum rectal dose or mean rectal dose was 7476 cGy and 6820 cGy in Group I and 6475 cGy and 6081 cGy in Group II, respectively.

Table 6. Incidence of Late Complications After Radiotherapy

	High Dose Rate ICR (%)	Low Dose Rate ICR (%)
Bowel complication	13/354 (3.7)	14/165 (8.4)
Mild	10 (2.8)	8 (4.8)
Moderate	3 (0.9)	6 (3.6)
Severe	0	0
Bladder complication	5/354 (1.4)	4/165 (2.4)

Table 7. Correlations Between Complications and Rectal Dose in the HDR-ICR Group

Variables	Group	No. of cases	Mean value (cGy)	2-tail prob.
ERT Dose (midline)	I*	341	2489	0.323
	II**	13	2189	
MRD	I	341	4987	0.293
	II	13	4256	
mRD	I	341	4331	0.507
	II	13	3892	

* Patients without complication
** Patients with complication
ERT : external irradiation MRD : maximum rectal dose
mRD : mean rectal dose

Our intrauterine tandem is not rigid and the ovoids and tandem are not fixed to each other, so the application pattern largely depended upon each patient's anatomical variation. As a result, the application pattern, such as cranio-caudad or anterior-posterior displacement of ovoid sources from tandem and deviation of tandem, usually retroverted, was significantly correlated with rectal doses. However, these variations did not affect the complication rate in this study.

DISCUSSION

The major advantages of the remotely controlled afterloading HDR-ICR system in the treatment of uterine cervical cancer are less radiation exposure to medical personnel, short treatment time and nonnecessity of hospitalization[1]. Therefore, the HDR-ICR system has been preferred in a countries where there is a high incidence of uterine cervical cancer, and a comparable cure rate and acceptable complication rate were reported. However, radiobiological aspects, such as the optimum number of fractionations, dose per fraction and an adequate external irradiation dose in relation to the ICR dose, have not yet been fully resolved. Although a major disadvantage of high-dose-rate is the rapid increase in incidence or risk of late reactions rather than the tumor cell-killing effect, it could be compromised by increasing the number of fractionations. Furthermore, there are biologic advantages such as re-oxygenation of hypoxic cells between fractions and accurate positioning of applicators during a short treatment time[1]. Therefore, a smaller dose per fraction is more effective radiobiologically, but too many fractionations can be time-consuming and cumbersome to the patients[2]. We chose a small fraction size, 300 cGy on point A, three times a week with a total of 30-39 Gy over 3-4 weeks and an early midline shield during external irradiation to reduce complications.

After the first clinical application of the HDR-ICR system in the treatment of uterine cervical cancer by Henschke in 1963[5], many institutions worldwide used their own protocols and reported their results (Table 8)[1,2,6~13]. Most reports concluded that HDR-ICR was a good alternative to LDR-ICR with a comparable survival rate and acceptable complication rate. However, the complication rate was somewhat higher in the studies which used a higher dose per fraction[13]. The present study also showed a similar survival rate with a very low complication rate which may be due to the early midline shield during external irradiation and the large number of fractionations in ICR. With this in mind, it is reasonable to think that it might be possible to achieve an improved survival rate with an acceptable complication rate by increasing the midline external irradiation dose with an appropriate midline shield according to the prognostic factors. Besides stage, several host factors, such as tumor volume, gross appearance of tumor, histologic type of tumor, uterine extension and several treatment factors, such as central and lateral dose, and use of intracavitary irradiation were well-known prognostic factors in patients receiving radiotherapy[14~16]. In the Patterns of Care Study (PCS) in the US, a definitely superior survival rate was noted in the extended survey group, especially in stage IIIB[14]. They used higher doses of radiation at both central and lateral dose points. Perez et al[15] also reported that higher doses of irradiation to the medial and lateral parametrium were correlated with a lower incidence of parametrial failure in stage IIA, IIB and III. These authors recommend a central dose at the level of 85-90 Gy[14,15]. However, complication rates were rapidly increased when rectal doses were higher than 80 Gy[17,18]. Although exact comparison between HDR dose and LDR dose is difficult, midline doses in the current study were thought to be suboptimum and less than the critical dose to produce complications. That might explain reason why rectal doses with or without complications were not different. Our ongoing protocol is to deliver 30-50 Gy at the midline and 45-60 Gy at the parametrium by external irradiation plus 30-48 Gy at point A by ICR according to the stage, tumor

Table 8. Dose–Fractionation Schedule and Treatment Results at Several Different Institutes

Institute	ICR		External RT			5yr survival (%)				Major complication rate (%)*
	Dose per fraction (Gy)	Fractionation	Total dose	Whole pelvis dose (Gy)	Mialine dose (Gy)	IB	IIA	IIB	III	
National Cancer Center, Tokyo, Japan	5	2 / wk	15 – 30 (mean 21.9)	28.5 – 66.5 (mean 50.3)				60	54	2.4 (26.4)
Osaka Univ. Hosp., Japan	8 – 10	1 / wk	25 – 30	40	20			60	52	(36)
Center for Adult disease Osaka, Japan	7.5	1 / wk	30 – 45	40 – 46	14 – 28	86	65	72	41	4 (11)
Tohoku Univ., Japan	6	1 / wk	30	50 – 60	40	97.4		55.1	56.8	24.1
Gothenburg, Sweden	8.5	1 / wk	42.5	0 – 10		88 (IB & IIA)				(4)
Ligue Contre le Cancer, Haiti	7.5	1 / wk	30	40						
Univ. Central Hosp., Turku, Finland	7.5 – 10	1–2 / wk	30 – 37.5	50	25 – 30	95.3		63.6		(27.7)
Velindre Hospital, United Kingdom	7 – 8.5	1 / wk	17 – 42.5	0 – 77.4	0 – 54	77	71	31%	25%	3 (8)
Yonsei Univ. Hospital, Seoul, Korea	3	3 / wk	30 – 39	44 – 48	20 – 30	78		68 (IIA & IIB)	51	0 (3.7)

* The figure in parenthesis denotes complication rates including minor complications.

volume, and response to radiation.

Because the uterine tandem and ovoids of our applicator are non-rigid and most Korean women have a retroverted uterus, the rectal dose (mean rectal dose) irradiated by ICR was relatively high and was greatly affected by the extent of posterior deviation of tandem. Also, the uterine tandem and ovoids are not fixed to each other and the prescribed dose was calculated on point A, so displacement of ovoids from the tandem affected the rectal dose as in the results reported by Teshima et al[19]. In this study, the cumulative rectal dose was relatively low due to minor contribution by external irradiation. Improvement of our applicator might also contribute to improving survival.

In conclusion, the HDR-ICR system with Co-60 in the treatment of uterine cervical cancer was not only convenient and safe, but also showed a comparable survival rate to that of conventional LDR-ICR. Therefore, the HDR-ICR system is highly recommended for a cancer center, particularly where a large number of patients must be treated. In order to achieve an improved outcome, however, the optimum dose-fractionation schedule of HDR-ICR and optimum combination of intracavitary irradiation with external radiation should be determined through an extensive protocol study with different treatment regimens.

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국문초록 =

고선량률 강내조사를 사용한 자궁경부암의 치료

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1979년 5월부터 1981년 12월까지 총 524명의 자궁경부암 환자가 근치적 목적하에 방사선 치료를 받았다. 524명의 환자중, 356명이 코발트 선원을 사용한 원격 조정 아프터로딩 고선량률 강내조사 시스템(Ralstron)으로써 치료받았으며 168명의 환자는 라듐 선원을 사용한 저선량률 강내 조사를 받았다. 외부조사는 골반부 전체에 총 40-50 Gy가 주어졌으며, 이어서 A지점에 10-13번에 걸쳐 30-39 Gy의 강내 조사를 시행하는 치료지침이 사용되었다. 강내조사는 3 Gy씩, 일주일에 세번 주어졌다.

고선량률 강내조사를 받은 군에서의 5년 실제생존률은 IB기 (N=20)가 77.6%, II기(N=182)가 68.2% 그리고 III기(N=148)가 50.9%였다. 저산량률 강내조사군에서의 5년 생존률은 IB기(N=22)가 87.5%, II기(N=91)가 66.3%, 그리고 III기(N=52)가 55.4%였다. 생존률은 병기에 따라서는 통계학적으로 유의한 차이를 보였지만, 두 강내조사군 간에는 유의한 차이가 없었다.

방사선치료후 내장의 후기 합병증은 고선량률 강내조사 군에서 3.7%, 저산량률 강내조사군은 8.4%에서 관찰되었다. 그러나 외과적 치료가 필요할 만큼 심한 합병증은 없었다. 방광에서 발생한 합병증의 빈도는 고선량률 강내조사군이 1.4%, 저선량률 강내조사군은 2.4%였다.

고선량률 강내조사의 시술은 외래 환자에 시행하기에 기술적으로 간단하고 쉬우며 마취가 필요없고, 환자가 매우 잘 견딘다. 담당자에 대한 방사선 피폭도 저선량률 강내조사에 비해 사실상 거의 없다. 고선량률 강내조사의 경우 치료시간이 짧기 때문에 주어진 시간내에 더 많은 환자를 치료할 수 있다. 따라서 많은 환자를 치료해야 되는 암센터의 경우, 고선량률 강내조사 시스템이 훨씬 더 권장되어 진다. 그러나 더욱 향상된 결과를 얻기 위하여, 다른 치료 방식으로 광범위한 연구를 통해, 고선량률 강내조사의 적절한 선량-분할조사 계획과 외부조사와 강내조사의 적절한 배합이 이루어져야 할 것이다.