Effects of Radiation Therapy on Immunological and Virological Status in HIV-Infected Cancer Patients in Thailand: A Multicenter Prospective Study

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Background: *Radiation therapy (RT) is the core part of cancer multidisciplinary management which causes myelosuppression. The current standard for RT among HIV-positive cancer patients who are immuno-compromised does not differ from that of HIV-negative ones.*
Objective: *To determine the effects of radiation therapy on immunological and virological status among HIV-infected cancer patients.*
Material and Method: *A prospective observational study was conducted of HIV-infected cancer patients who received definitive RT in seven hospitals in Thailand. Blood samples were taken to determine immune status using CD4%, and virological status was identified using plasma HIV-RNA viral load (HIV-VL) assay: at baseline before RT; at the last week of RT completion; and at the 6-month follow-up visit. Additional CD4% test was performed at the 3-month follow-up visit.*
Results: *Ninety HIV-infected cancer patients from seven hospitals in Thailand were included in the analysis. The median age was 40 years old (range 19-61). Seventy-six patients (84.4%) were female and 65 (72.2%) were cases of invasive cervical cancers. Eighty-seven percent of patients had been receiving antiretroviral treatment (ART) before RT. The mean CD4% at baseline, RT completion, 3-month and 6-month follow-up visits, were 18.7%, 20.1%, 16.8% and 17.1%, respectively. The proportion of CD4% reduction in the non-ART group was higher than that of the ART group throughout the period, particularly at the 3-month follow-up visit (100% vs. 29.7%, p = 0.0004). Six cases had a HIV-VL increase of more than 10 times (1-$\log_{10}$) at completion of RT: 3 of these were non-ART, and 3 were ART-uncontrolled viral suppression.*
Conclusion: *RT had a suppressive effect on immunological status in HIV-infected cancer patients, particularly in the subacute period among those who were not on ART. HIV-disease progression was observed during radiation treatment in HIV-infected cancer patients without ART and those with ART-uncontrolled viral suppression.*

Keywords: *Cancer, Radiation therapy, AIDS, HIV, Antiretroviral, Immunosuppression*

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Since the advent of the era of antiretroviral treatment, mortality rates in the HIV-positive population have decreased remarkably. The incidence of AIDS-associated malignancies and also non-AIDS-associated malignancies has been higher in HIV-positive individuals than in the normal population[1,2]. In the HIV-positive population, the incidence of invasive cervical cancer has increased in Africa and Asia (including Thailand), together with head and neck cancer and breast cancer in other regions[3-5].

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Radiation therapy (RT) is a core part of cancer multidisciplinary management especially in invasive cervical cancer. The current standard for RT among HIV-positive and immunocompromised patients does not differ from that used for HIV-negative patients[6]. Radiation therapy causes myelosuppression with a decrease in white blood cell count and lymphocytes. It also changes the absolute number of CD4 count due to the associated parameters of lymphocyte calculation, whereas the percentage of CD4 (CD4%) undergoes only minimal changes. CD4% should be used to determine immune status during RT[7].

An understanding of immune status through CD4% and virological status in HIV-infected cancer patients during RT will help to improve management of patients. This study presents the results of HIV-infected cancer patients who received definitive RT and HIV treatment in accordance with the Thailand National ART guidelines of 2008[8].

Material and Method

This prospective observational study was conducted in the Therapeutic Radiology and Oncology Units of seven hospitals in Thailand. The protocal was reviewed and approved by the ethics committees of Rajavithi Hospital (No. 78/2552) and the other study centers. The inclusion criteria were patients who were HIV-positive with pathologically proven carcinoma or lymphoma, and who were aged between 18 and 65 years. All patients received definitive RT using conventional fraction external beam RT of at least 40 grays (Gy). Brachytherapy and concurrent chemoradiation were applied according to standard guidelines. The exclusion criteria were patients who had CD4 count of less than 200 cells/cu.mm. at baseline without antiretroviral treatment, and patients who were not assessed for CD4% or HIV-viral load (HIV-VL) at the completion of RT.

Immune status using complete blood count, CD4% and virological status using HIV-VL were determined at baseline, the last week of RT completion, and 6 months after completion of RT. Complete blood count and CD4% were additionally assessed 3 months after RT completion. CD4 reduction was considered to have occurred when CD4% decreased by 3%. The CD4 and HIV-VL tests were performed using the flow cytometry technique and branched DNA polymerase chain reaction (PCR) respectively. HIV-VL were categorized into 3 groups to determine HIV-disease progression: ≤50 copies/mL (complete viral suppression); 51-1,000 copies/mL (fair viral suppression); and >1,000 copies/mL (uncontrolled viral suppression). Statistical analysis was carried out for descriptive and inferential statistics with mean, median, percentage, and Chi-square test for comparing differences in immunological status between the ART and non-ART groups with statistical significance set at 0.05, using Epi info™ version 3.5.4. Mixed effects models were used to compare mean changes in CD4% over time using STATA™ version 8.0.

Results

Ninety-nine patients were recruited from August 22, 2009 to July 31, 2012. Nine cases were excluded from the analysis (7 because of incomplete RT or a change to palliative aims, and the other 2 cases because of missed laboratory tests at RT completion); therefore, a total of 90 cases were included in the analysis. The median age was 40 years (range 19-61 years), and seventy-six cases (84.4%) were female. The median CD4% was 18.0% (range 3.0-44.9%), and seventy-nine cases (87.8%) had been receiving antiretroviral treatment (ART) before RT. Sixty-three cases had been on ART for less than 3 months before RT in the period of cancer diagnosis and staging, and sixteen cases had been on ART for more than 3 months before RT. Median HIV-VL was 40 copies/mL (range 20-630,957 copies/mL). Fifty-nine cases (74.7%) who were on ART had complete viral suppression (HIV-VL ≤50 copies/mL), eleven (13.9%) had fair viral suppression (51-1,000 copies/mL) and nine (11.4%) had baseline HIV-VL >1,000 copies/mL of which 6 cases had been on ART for less than 3 months, and 3 cases had been on ART for more than 1 year. Baseline data are shown in Table 1.

Sixty-five cases (72.2%) were invasive cervical cancers. They received conventional external-beam RT 50 Gy for early-stage invasive cervical and 54-56 Gy for locally-advanced stage. Intracavitary brachytherapy dosages were 6.5-7.5 Gy/fraction, 3-4 fractions according to individual hospital protocals. Thirty-five invasive cervical cancer patients received platinum-based concurrent chemoradiation. There were 9 head and neck cancers, 5 breast cancers, 4 vaginal cancers, 2 non-Hodgkin's lymphomas, and one case each of esophageal cancer, penile cancer, vulva cancer, anal cancer and brain lymphoma. Radiation therapy was performed according to standard clinical practice guidelines. Invasive cervical cancer, head and neck cancer, and prostate cancer underwent radiation periods of 6-7 weeks. Breast cancer and lymphoma had shorter radiation periods than other cancers, not exceeding 5

Table 1. Characteristics and baseline informations of study population (90 cases)

Patient characteristics	Number (%)		
	ART (n = 79)	Non-ART (n = 11)	Total (n = 90)
Sex			
Female	65 (82.3)	11 (100)	76 (84.4)
Male	14 (17.7)	0 (0)	14 (15.6)
Age (years) median 40, range 19-61			
18-39	40 (50.6)	3 (27.3)	43 (47.8)
≥40	39 (49.4)	8 (72.7)	47 (52.2)
CD4 count (cells/cu.mm.) median 334, range 30-989			
<200	19 (24.1)	0 (0)	19 (21.1)
200-349	22 (27.8)	2 (18.2)	24 (26.7)
350-499	19 (24.1)	4 (36.3)	23 (25.6)
≥500	19 (24.1)	5 (45.5)	24 (26.7)
CD4 % median 18.0%, range 3.0-44.9%			
<10.0%	14 (17.7)	0 (0)	14 (15.6)
10.0-19.9%	31 (39.3)	6 (54.5)	37 (41.1)
≥20%	34 (43.0)	5 (45.5)	39 (43.3)
HIV-VL (copies/mL) median 40, range 20-630,957			
≤50	59 (74.7)	0 (0)	59 (65.6)
51-1,000	11 (13.9)	1 (9.1)	12 (14.4)
>1,000	9 (11.4)	10 (90.9)	19 (24.1)
Duration of ART at baseline			
<3 months	63 (80.8)	-	-
≥3 months	16 (19.2)	-	-

ART = antiretroviral treatment; HIV-VL = HIV-RNA viral load

Table 2. Types of cancer and treatment in HIV-infected cancer patients

Cancer	Number	EBRT (grays)	CCRT, n (%)	ART, n (%)
Cervix	65	50-60	35 (53.8)	54 (83.1)
Head and neck	9	66-70	4 (44.4)	9 (100)
Breast	5	50-60	0 (0)	5 (100)
Pelvic organs excluding cervix	7	50-70	3 (42.8)	7 (100)
Others	4	40-56	0 (0)	4 (100)
Total	90	40-70	42 (46.7)	79 (87.7)

EBRT = external-beam radiation therapy; CCRT = concurrent chemoradiation therapy (platinum-based regimens); ART = antiretroviral treatment

weeks. The details of external-beam RT, chemotherapy, and ART by cancer sites are shown in Table 2.

The mean CD4% of all patients at baseline, RT completion, 3-month, and 6-month follow-up after RT completion were 18.7%, 20.1%, 16.8% and 17.1% respectively, and the change of mean CD4% during treatment and follow-up period was statistically significant ($p = 0.003$). The duration of RT varied from 5-7 weeks, and CD4% at RT completion and follow-up is shown in Fig. 1.

At the last week of RT completion, 21/90 cases (23.3%) had CD4% reduction of more than 3% compared to baseline. Eight cases were lost to follow-up at the 3-month follow-up visit. The proportion of

CD4% reduction increased at the 3-month follow-up visit compared to baseline in 29/81 cases (35.8%). All seven cases in the non-ART group had CD4% reduction of over 3% at the 3-month follow-up visit. At the 6-month follow-up after RT completion, a total of 18 cases were lost to follow-up, two cases missed CD4 test, and 21/70 cases (30.0%) had CD4% reduction compared with the baseline. The data are shown in Table 3.

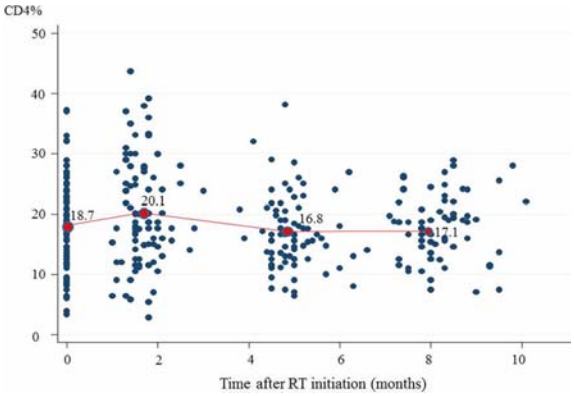

Fig. 1 Mean CD4% change in HIV cancer patients received radiation therapy by time.

Regarding HIV-disease at RT completion, 71 ART cases had complete viral suppression. Of these 71 cases, 11/20 who had fair and uncontrolled viral suppression at baseline converted to complete viral suppression during RT. Eight cases still had fair viral suppression (5 cases in the ART group and 3 cases in non-ART group). Eleven patients who had uncontrolled viral suppression at the time of RT completion were cases of invasive cervical cancer (3 and 8 cases in the ART group and non-ART group respectively). Details are shown in Table 4. In the 8 non-ART patients, 3 cases had HIV-VL elevated more than 1-log or 10-times. The details of each case with increased HIV-VL at RT completion are described in Table 5, cases 1-11.

At the 6-month follow-up visit, 66 cases had HIV-VL data, while 18 cases were lost to follow-up, and

Table 3. Immunological status after radiation therapy completion

Period	Reduction of CD4% >3% compared to baseline (x)			*p*-value
	All x/n (%)	ART group x/n (%)	Non-ART group x/n (%)	
RT completion	21/90 (23.3)	16/79 (18.9)	5/11 (45.5)	0.0760
3-month follow-up	29/81 (35.8)	22/74 (29.7)	7/7 (100.0)	0.0004
6-month follow-up	21/70 (30.0)	17/64 (26.2)	4/6 (66.7)	0.0620

ART = antiretroviral treatment
Statistically significant for Chi-square test using *p*-value <0.05

Table 4. Virological status after radiation therapy

Period	HIV-RNA viral load (copies/mL)	All cases, n	ART group, n (%)	Non-ART group, n (%)
Baseline	≤50	59	59 (100)	0 (0)
	51-1,000	12	11 (91.7)	1 (8.3)
	>1,000	19	9 (47.4)	10 (52.6)
RT completion	≤50	71	71 (100)	0 (0)
	51-1,000	8	5 (62.5)	3 (37.5)*
	>1,000	11	3 (27.3)	8 (72.7)
6-month follow-up**	≤50	58	55 (94.8)	3 (5.2)*
	51-1,000	1	1 (100)	0 (0)
	>1,000	7	3 (42.9)	4 (57.1)

ART = antiretroviral treatment
* Start ART before HIV-VL assessment; ** 18 cases lost to follow-up, 6 cases missed tests

Table 5. Treatments and virological parameters (HIV-VL) of HIV cancer patients with increased HIV-VL in ART and non-ART cases

No.	RT dose (Gy)	ART (duration)	CD4% baseline	HIV-VL (copies/cu.mm.)		
				Baseline	RT completion	6-month FU
1	54	GPO-VIRS30 (7 year)	16.0	1,861	283,087	1,835,633
2	56	EFV, 3TC, d4T (2 year)	14.0	1,830	10,576	Loss FU
3	50	GPO-VIRS30 (1 year)	8.3	863	4,330	957
4	50	No	37.0	150,247	306,095	600,214
5	56	No	13.0	74,370	163,224	Loss FU
6	54	No	17.1	30,100	1,080,000	Loss FU
7	50	No	32.2	7,440	16,187	25,670
8	50	No	36.1	7,101	17,400	10,235
9	56	No	14.0	5,886	39,772	Loss FU
10	56	No	18.0	7,056	76,862	45*
11	50	No	19.9	56	142,000	20*
12	56	No	23.0	3,190	1,400*	40
13	56	No	21.9	630,957	276,327*	2,571
14	56	No	17.0	7,741	313*	Loss FU

RT = radiation therapy; ART = antiretroviral treatment; GPO-VIRS30 = d4T 30 mg plus 3TC plus Nevirapine in a single tablet; EFV = Efavirenz; d4T = Stavudine; 3TC = Lamivudine; FU = follow-up
* Start ART before HIV-VL assessment

6 cases missed HIV-VL tests. In the ART group, 55 cases had complete viral suppression, one case had fair viral suppression, and 3 cases had uncontrolled viral suppression (Table 4). In the non-ART group, 3/5 cases who were started ART converted to completed viral suppression, as described in Table 5, cases 10-14.

Discussion

This study was a prospective cohort of fairly large numbers of HIV cancer patients from various regions in Thailand, and about three-quarters of cases were invasive cervical cancer, which is the most common cancer in HIV-populations in Africa and Asia[3-5]. The treatment of choice in HIV-infected invasive cervical cancer is RT or concurrent chemoradiation to the pelvic region[9]. RT has generalized effects on hematopoietic bone marrow function, not limited to the pelvic bone alone. The overall treatment time of definitive RT varies from 5 to 7 weeks depending on cancer sites.

This study used CD4% and HIV-VL as markers for immunological status and virological status respectively. The CD4% and HIV-VL were recorded at the last week of RT completion, 3 months and 6 months after completion of RT, representing acute, subacute and late radiation effects respectively. At the last week of RT completion, mean CD4% had a minimal increase from the baseline (18.7% to 20.1%), and this increase of CD4% might have been due to starting ART within 3 months of RT. Most ART cases (76/79 cases) who were on ART during RT had no HIV-disease progression during RT. Twelve ART cases were able to convert to complete viral suppression, while the non-ART group and the ART-uncontrolled viral suppression group had HIV-disease progression during RT. There were 3 ART cases with uncontrolled viral suppression who had received ART for more than 1 year without changing drug regimens.

The highest level of immunosuppression was at the 3-month follow-up visit (35.8%) with the lowest mean CD4% at 16.8%. Radiation therapy suppressed immune responses in the non-ART group more than the ART group at every period, with statistical significance ($p = 0.0004$) at the 3-month period after completion of RT. In 2014, Fraunholz reported that the CD4 count significantly decreased 3-7 weeks after complete chemoradiation ($p<0.001$)[10]. Immunosuppression seems to decline 6 months after completion of RT (30.0%) with CD4% at 17.1%. The following HIV-VL tests were done only at 6-month follow-up visit, in accordance with the 6-month evaluation recommended in ART guidelines[10]. There was inadequate evidence to prove that the maximum immunosuppression happened at the 3-month follow-

up visit or subacute radiation effect. Radiation therapy did not produce acute radiation effects on immunological and virological status in HIV cancer patients who had recently started ART (within 3 months). Three non-ART cases who were started on ART were able to control HIV-VL in the short duration of the 6-month follow-up visit.

This study observed HIV-disease progression during RT only in the non-ART group; in addition, there were 3 cases of ART-uncontrolled viral suppression in patients with invasive cervical cancers. There was no HIV-disease progression during RT in patients who had good viral suppression at baseline. Furthermore, the introduction of ART before RT and reassessment of HIV-VL in the long-term ART group was able to reduce HIV-VL during RT. We recommend initiating ART before applying RT for all HIV-infected cancer patients. In Thailand, the new HIV treatment guidelines for 2015 recommend providing ART to all HIV-infected patients regardless of their CD4 level[11]. HIV-infected patients with good tolerance who undergo ART should normally receive definitive radiation therapy as a standard approach, identical to non-HIV patients[12,13].

Conclusion

Definitive RT brought about significant suppression of immunological status in HIV-infected cancer patients. The immune suppression in the non-ART cancer patients was higher than that in the ART group with a statistically significant difference in subacute period. HIV-disease progression was observed during radiation among cancer patients without ART and those with ART-uncontrolled viral suppression.

What is already known on this topic ?

RT has generalized effects on hematopoietic bone marrow function and causes a reduction in white blood cell count and lymphocytes while the percentage of CD4 (CD4%) has minimal changes. The CD4% should be used to determine immune status during RT. The CD4 count of HIV-infected anal-cancer patients significantly decreases 3-7 weeks after complete chemoradiation.

What this study adds ?

RT had suppression effect on immunological and virological status in HIV-infected cancer patients. The immune suppression in non-ART group was higher than ART group in subacute period. HIV-disease progression was observed during RT only in the non-ART group and ART-failure patients

The introduction of ART before and during RT was able to reduce HIV progression during RT. We recommend initiating ART before applying RT to HIV-infected cancer patients.

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Potential conflict of interest

None.

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ผลกระทบจากการฉายรังสีต่อภาวะภูมิคุ้มกันและปริมาณไวรัสเอชไอวีในผู้ป่วยมะเร็งที่ติดเชื้อเอชไอวีในประเทศไทย: การศึกษาไปข้างหน้าแบบสหสถาบัน

ปฐมพร ศิรประภาศิริ, เอกสิทธิ์ ธราวิจิตรกุล, นันทน์ สุนทรพงศ์, ช่อแก้ว โตวณะบุตร, เอกภพ หมื่นนุช, พิมพ์พรรณ ปานบุญ, ธิติ สว่างศิลป์, ทวีทรัพย์ ศิรประภาศิริ

ภูมิหลังและวัตถุประสงค์: *รังสีรักษาเป็นส่วนสำคัญของการการรักษามะเร็งซึ่งส่งผลกดการทำงานของระบบการสร้างเม็ดโลหิต ปัจจุบันมาตรฐานการฉายรังสีรักษาในกลุ่มผู้ป่วยที่มีภาวะภูมิคุ้มกันบกพร่องไม่มีความแตกต่างกันกับผู้ป่วยที่ไม่ติดเชื้อเอชไอวี จึงทำการศึกษาผลกระทบของการฉายรังสีต่อภาวะภูมิคุ้มกัน และปริมาณไวรัสเอชไอวีในผู้ป่วยมะเร็งที่ติดเชื้อเอชไอวีที่ได้รับการฉายรังสี*

วัสดุและวิธีการ: *การศึกษาแบบสังเกตุไปข้างหน้าในผู้ป่วยมะเร็งที่ติดเชื้อเอชไอวี และได้รับการฉายรังสีแบบหวังผลหายขาดในโรงพยาบาล 7 แห่งของประเทศไทย โดยทำการตรวจเลือดเพื่อหาร้อยละของเม็ดเลือดขาวซีดี 4 และปริมาณไวรัสเอชไอวีในกระแสเลือดก่อนการฉายรังสี สัปดาห์สุดท้ายที่ฉายรังสีครบกำหนด และในการตรวจติดตามหลังการฉายรังสีเสร็จสิ้น 6 เดือน และมีการตรวจหาร้อยละเม็ดเลือดขาวซีดี 4 เพิ่มเติมในการตรวจติดตามหลังการฉายรังสีเสร็จสิ้น 3 เดือน*

ผลการศึกษา: *ผู้ป่วยมะเร็งที่ติดเชื้อเอชไอวีจาก 7 โรงพยาบาลในประเทศไทยจำนวนทั้งสิ้น 90 รายได้รับการคัดเข้าสู่การวิเคราะห์ ผลการศึกษาพบว่าผู้ป่วยมีค่ามัธยฐานอายุ 40 ปี (ช่วงอายุระหว่าง 19-61)) เป็นผู้หญิง 76 ราย คิดเป็นร้อยละ 84.4 ส่วนใหญ่ป่วยเป็นมะเร็งปากมดลูก 65 ราย (ร้อยละ 72.2) ผู้ป่วยส่วนใหญ่ได้รับยาต้านไวรัสก่อนการฉายรังสีร้อยละ 87.8 สำหรับค่าเฉลี่ยร้อยละของเม็ดเลือดขาวซีดี 4 ก่อนการฉายรังสี หลังการฉายรังสี และในการตรวจติดตามหลังการฉายรังสีเสร็จสิ้น 3 และ 6 เดือน คือร้อยละ 18.7, 20.1, 16.8 และ 17.1 ตามลำดับ สัดส่วนการลดลงของร้อยละของเม็ดเลือดขาวซีดี 4 ในกลุ่มที่ไม่ได้รับยาต้านไวรัส มากกว่ากลุ่มที่ได้รับยาต้านไวรัสอย่างมีนัยสำคัญทางสถิติ ในช่วงการตรวจติดตามหลังการฉายรังสีเสร็จสิ้น 3 เดือน (ร้อยละ 100 เทียบกับร้อยละ 29.7 ค่านัยสำคัญทางสถิติ 0.0004) ผู้ป่วย 6 รายมีเชื้อไวรัสเอชไอวีเพิ่มขึ้นมากกว่า 10 เท่าหลังการฉายรังสี โดยผู้ป่วย 3 รายไม่ได้รับยาต้านไวรัสและ 3 รายได้รับยาต้านไวรัสมาก่อนแต่ไม่สามารถควบคุมเชื้อเอชไอวีได้*

สรุป: *รังสีรักษามีผลกดภาวะภูมิคุ้มกันในผู้ป่วยมะเร็งที่ติดเชื้อเอชไอวี โดยเฉพาะในช่วง 0-3 เดือนหลังการฉายรังสีในกลุ่มผู้ป่วยที่ไม่ได้รับยาต้านไวรัส การดำเนินโรคของเอชไอวีที่รุนแรงขึ้น พบในผู้ป่วยมะเร็งที่ติดเชื้อเอชไอวีซึ่งไม่ได้รับยาต้านไวรัสหรือได้รับยาต้านไวรัสมาก่อนแต่ไม่สามารถควบคุมเชื้อเอชไอวีได้*