RESEARCH ARTICLE

Comparisons between the KKU-Model and Conventional Rectal Tubes as Markers for Checking Rectal Doses during Intracavitary Brachytherapy of Cervical Cancer

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Abstract

Background: To compare the KKU-model rectal tube (KKU-tube) and the conventional rectal tube (CRT) for checking rectal doses during high-dose-rate intracavitary brachytherapy (HDR-ICBT) of cervical cancer. Materials and Methods: Between February 2010 and January 2011, thirty -two patients with cervical cancer were enrolled and treated with external beam radiotherapy (EBRT) and intracavitary brachytherapy (ICBT). The KKU-tube and CRT were applied intrarectally in the same patients at alternate sessions as references for calculation of rectal doses during ICBT. The gold standard references of rectum anatomical markers which are most proximal to radiation sources were anterior rectal walls (ARW) adjacent to the uterine cervix demonstrated by barium sulfate suspension enema. The calculated rectal doses derived from actual anterior rectal walls, CRT and the anterior surfaces of the KKU-tubes were compared by using the paired t-test. The pain caused by insertion of each type of rectal tube was assessed by the visual analogue scale (VAS). Results: The mean dose of CRT was lower than the mean dose of ARW ($Dmean_0$-$Dmean_1$) by 80.55±47.33 cGy (p-value <0.05). The mean dose of the KKU-tube was lower than the mean dose of ARW ($Dmean_0$-Dmean2) by 30.82±24.20 cGy (p-value <0.05). The mean dose difference [($Dmean_0$-$Dmean_1$)-($Dmean_0$-$Dmean_2$)] was 49.72±51.60 cGy, which was statistically significant between 42.32 cGy -57.13 cGy with the t-value of 13.24 (p-value <0.05). The maximum rectal dose by using CRT was higher than the KKU-tube as much as 75.26 cGy and statistically significant with the t-score of 7.55 (p-value <0.05). The mean doses at the anterior rectal wall while using the CRTs and the KKU-tubes were not significantly different (p-value=0.09). The mean pain score during insertion of the CRT was significantly higher than the KKU-tube by a t-score of 6.15 (p-value <0.05) Conclusions: The KKU-model rectal tube was found to be an easily producible, applicable and reliable instrument as a reference for evaluating the rectal dose during ICBT of cervical cancer without negative effects on the patients.

Keywords: KKU-model rectal tube - rectal dose - intracavitary brachytherapy - cervical cancer

Asian Pac J Cancer Prev, **15 (15)**, 6115-6120

Introduction

Cervical cancer is the most common gynecologic malignancy in Thai women and more than 50 percent of cases have died from cervical cancer; an average of nearly 3000 cases per year, or about 7 cases per day. There were more than 270,000 people worldwide die with this disease each year or 650 people per day by estimation.

From the report of the Thai National Cancer Institute (Thai National Cancer Institute, 2009), the Ministry of Health of Thailand reported that by the year 2007, the incidence of cervical cancer was 24.7 per 100,000 of Thai women, or 6,243 new cases per year on an average. It was considered to be the most common cancer in Thai women. In Khon Kaen, a province in the northeastern Thailand, the incidence of cervical cancer was about 18.0 per 100,000 of the female population.

In Srinagarind hospital, there were 7.9% or 217/2752 cases of cervical cancer of the overall cases of female cancers (Wiangnon et al., 2012). More than half of the cases were of the locally advanced stage, so the combination of external beam radiotherapy (EBRT) and intracavitary brachytherapy (ICBT) is the treatment of choice. The bladder and rectum injuries from high radiation doses leads to morbidity and poor quality of life (Eng et al., 2004). The main treatmen-related factors which influence late complications were brachytherapy dose rate, volume of irradiated rectum and overall rectum dose (Montanna and Fowler, 1989; Van Lanker and Storme, 1991; Clark et al., 1994; Hai-Meder et al., 1994). The total

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rectal dose must be kept as low as possible during ICBT to prevent rectal complications. The dosimetric variation on the dose-effect depends on the prescribed dose level for a specific target or organs at risk (OAR), and is an accurate surrogate for volumetric dose assessment (Stewart et al., 2008; Nesvacil et al., 2013) The late complications of radiation induced proctitis grades I, II and III were 26.9% (38/141 cases), 10.64% (15/141 cases) and 0.71% (1/141 case) after radiation therapy for cervical cancer (Pesee et al., 2010). During ICBT, the surrounding critical organs, especially the rectum and bladder must be separated away from the radioactive sources by intensive vaginal packing with vaseline gauze to prevent radiation proctitis and cystitis. Foley's catheter was introduced into the bladder and pulled down against bladder neck after the balloon was filled with 10 ml. contrast media for outlining the most adjacent bladder wall to uterine cervix.

The objectives of this study were to determine the reliability of KKU-tube for checking the rectal dose as compared to CRT and ARW and determining negative effects on the rectal dose and discomfort to the patients.

Materials and Methods

This study was a prospective cohort study in 32 cervical cancer patients enrolled between February 2010 and January 2011. All of them were treated with external beam radiotherapy(EBRT) and ICBT at the Division of Radiotherapy, Srinagarind Hospital, Faculty of Medicine, Khon Kaen University,Thailand. This study had been approved by the Human Ethics Committee of Khon Kaen University (HE 531279). Two different rectal tubes were inserted intrarectally as references for checking rectal doses during ICBT by both CRT and KKU-tubes in the same patients on alternate sessions.

Inclusion criteria for enrolled patients: *i*) Patients aged ≤70 years old with diagnosis of locally advanced cervical cancer stage IB2-IVB who were treated with EBRT and ICBT; *ii*) Karnofsky performance status (KPS) ≥60%; *iii*) The enrolled patients must sign consent form.

Exclusion criteria: *i*)Patients with rectal or perianal ulcer or cancer; *ii*)Poor Karnofsky performance status (<60%).

For checking the rectal dose, different types of rectal tubes with radio-opaque markers were applied intrarectally as references for evaluation of rectal doses. The standard method for locating the adjacent anterior rectal wall (ARW) based on ICRU 38 (International Commission on Radiation Units and Measurements report No.38, 1985) is performed by packing contrast-soaked gauze into the vagina. Then, orthogonal X-ray films of pelvis were taken. The reference point of the rectal wall was determined by adding 0.5 cm. from the posterior vaginal wall demonstrated by the contrast gauze in the vagina at the level of uterine cervix. There are many methods to determine the adjacent rectal wall such as filling the rectum by using a radio-opaque medium (Barium contrast) or insertion of a rectal tube filled with metal pellets. In Srinagarind Hospital, rectal tubes filled with metal pellets are called conventional rectal tubes (CRT) (Pesee et al., 2010; 2010; 2012; 2013). These were used as references for evaluation of the rectal dose as shown in Figure 1. The CRT has been used since 1986 until present, but the uncertainty of the CRT position in the rectal lumen could lead to an underestimation of the rectal dose and an unawareness of an overdose to the rectum. Therefore, a special rectal tube, called the KKU-model rectal tube (KKU-tube) was developed and used as a marker for checking rectal doses.

Most cases of uterine cervical cancer were initially treated by EBRT using telecobalt or with the 6MV linear accelerator to the whole pelvis at a total dose of 4,500-5,000cGy, 180-200cGy/fraction, 5 fractions/week. Then, the gross tumors in the parametrium involved were boosted with 600-1,000cGy/3-5 fractions of small field radiation, depending on the tumor extension. A midline shield for minimizing rectal and bladder doses might be used after 40Gy to the whole pelvis, depending on stage or tumor volume. Point A was used as reference for prescription of treatment doses from the report of ICRU

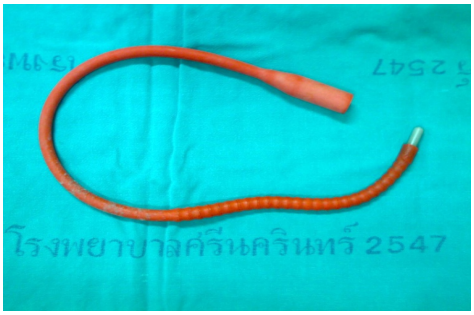

Figure 1. Conventional Rectal Tube(CRT) Containing Round Metal Pellets

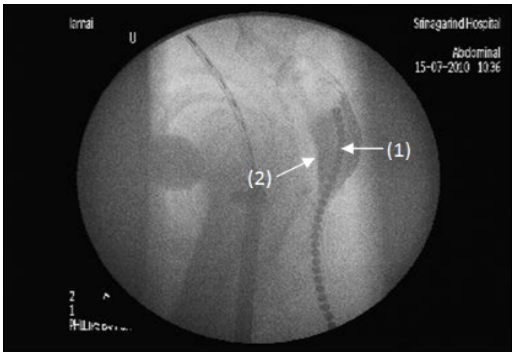

Figure 2. The Contrast-Coated CRT Rectal Radiograph Demonstrated the Location of the Conventional Rectal Tube (1) Which Was Far away from the Anterior Rectal Wall (2)

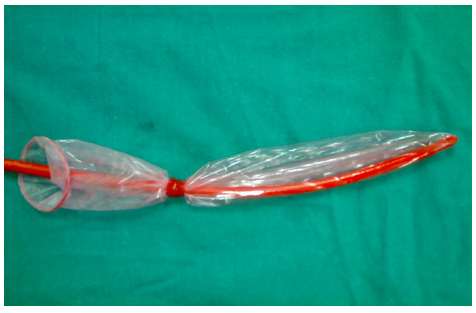

Figure 3. The KKU-Model Rectal tube(KKU-tube) using Nelaton's Catheter Combined with a Condom and Rubber Bands

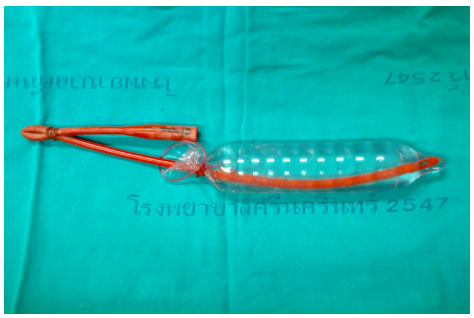

Figure 4. The KKU-model Rectal Tube Filled with 50ml. Contrast Medium in the Condom

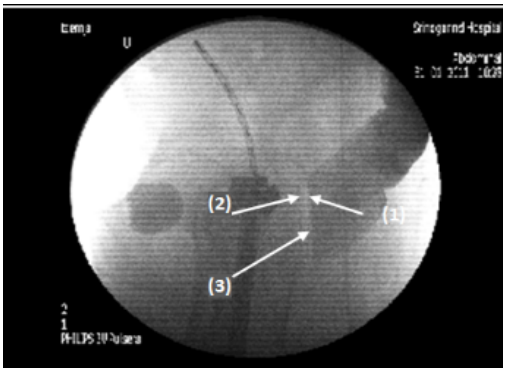

Figure 5. The Contrast-Coated KKU-tube Rectal Radiograph Demonstrated the Location of Anterior Surface of the KKU-tube (1) Which was Close to Anterior Rectal Wall (2). The Arrow 3 Shows Air Gap in the Condom

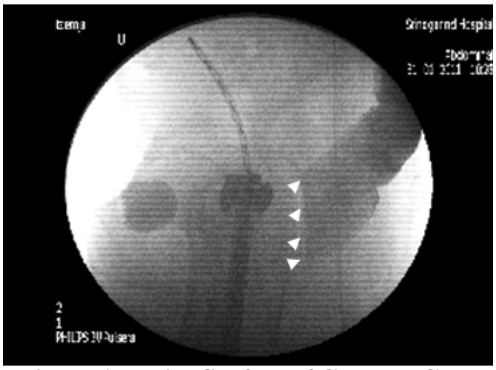

Figure 6. The Anterior Surface of Condom Close to the Uterine Cervix Marked as a Reference for Calculation of the Rectal Dose

No.38. ICBT was usually performed during or after complete EBRT by a remotely controlled high-dose-rate (HDR) brachytherapy machine (Varisource®)with 600 -650cGy at point A, weekly for 4 fractions.

After applicator insertion for ICBT, vaginal packing with vaseline gauze was applied to fix the applicators and pushed into the rectum and bladder away from these applicators. The rectal wall was coated with 30ml of barium contrast solution for outlining the actual anterior rectal wall (ARW). Then the CRT or KKU-tube were lubricated with gel and inserted into rectum as the markers for checking rectal doses on alternate weeks for each patient, using CRT at the 1st and 3rd weeks and KKU- tube at the 2nd and 4th weeks. The KKU- tube was developed by using Nelaton's catheter combined with a condom and rubber bands as shown in Figure 3. After the KKU-tube was inserted into the rectum, 50 ml. of contrast media (20% potassium iodine 10 ml. +40 ml sterile water) was injected into condom by an irrigating syringe through the proximal end of Nelaton's catheter until the condom was fully distended to contact the rectal wall. The anterior surface of condom at the level of cervix was used as the landmark for checking the rectal dose as shown in Figure 6. The CRT was made of Nelaton's catheter containing metal pellets as shown in Figure 1. The pellets in the rectal tube at the level of cervix were used as markers for checking rectal dose. Then, orthogonal X-ray films of pelvis were carried out for treatment planning using the Eclipse Varian system, Version 10 software.

During treatment planning, 4-6 points on the ARW which were most proximal to the radioactive sources were marked on both anterior and lateral radiographs as shown in Figure 6. Then the reference points were selected symmetrically in relation to radiographs from the CRT(R) and the KKU-tubes (Rref) for calculating the rectal doses. The radiation doses at reference points of both types of rectal tubes were compared with the actual doses at ARW. The different radiation doses from each rectal tube and ARW were recorded. The discomfort of the patients during each tube insertion was assessed in terms of pain by using the visual analogue scale (Hartrick et al., 2003). Comparisons between rectal doses of CRT ($Dmax_1$ and $Dmean_1$) and the doses using the KKU-tube ($Dmax_2$ and $Dmean_2$) were analyzed by using the paired t-test. A p-value of ≤0.05 was considered to be statistically significant. The analysis of the data was done by using software STATA+ version10.

Results

The patient characteristics are shown in Table 1. Most of the patients were stage IIB-IIIA , grade II diseases.

The differences of mean doses ($Dmean_0$-$Dmean_1$) and maximum doses ($Dmax_0$-$Dmax_1$) were strikingly higher

Table 1. Characteristics of 32 Patients with Cervical Cancer

Characteristics		No. of patients (%)
Age (Years)	<45	21.90
	>45-59	56.20
	60-70	21.90
Stage	I	0.00
	IIA	3.20
	IIB	40.60
	IIIA	50.00
	IIIB	6.20
	IVA	0.00
	IVB	0.00
Grade	1	15.60
	2	68.80
	3	15.60
Whole pelvis irradiation	5,000 cGy	93.80
	<5,000 cGy	6.20
Parametrial boost	Left: 600 cGy	6.20
	1,000cGy	18.80
	Right: 600 cGy	3.10
	1,000cGy	25.00
Residual tumor before ICRT	<1 cm	3.10
	1-2 cm	31.30
	>2 cm	31.30

than ARW and the KKU-tube. The maximal rectal doses in the same patients while using CRT (Dmax1) and KKU-tubes ($Dmax_2$) are shown in Table 2.

Statistics

The mean doses of the conventional rectal tubes were lower than the mean doses of the rectal wall by 80.55 cGy with a standard deviation of 47.33 (95%CI: 73.75-87.34). The mean dose of the KKU-tube was lower than the mean dose of rectal wall by 30.82 cGy with a standard deviation of 24.20 (95%CI: 27.24-34.29). The paired t-test was used to compare the differences of radiation doses between the rectal wall and both types of rectal tubes. The mean difference was 49.72 cGy with a standard deviation of 51.60 (with 95% confidence interval), which was statistically significant between 42.32 cGy -57.13 cGy with the t-score of 13.24 (p-value <0.05) (Table 3).

The differences of maximum radiation doses between the rectal wall and both rectal markers are compared in Table 3. The maximum dose differences between rectal wall and CRT is 103.50 cGy and the KKU- tube is 28.29 cGy, therefore, it is more likely to underestimate of the maximum rectal dose by using CRT as compared to the KKU-tube as much as 75.26 cGy which was statistically significant with the t-score of 7.55, p-value <0.05 (Table 3).

The mean actual rectal doses in the case when using the CRT or the KKU-tube were 398.76 cGy and 410.64 cGy (Table 3). The mean actual rectal dose in case using KKU-tube was only 11.89 cGy higher than patients using CRT which was not significant (p-value 0.09; 95%CI -25.77-2.00 cGy). The KKU-tube therefore had no significantly negative effect on actual rectal dose as compared to CRT (Table 3).

The pain visual analogue scale was used for assessment of discomfort in terms of pain from using either type of rectal tubes. The mean pain score of the CRT is 2.23 and KKU- tube is 1.55. The mean pain score of the conventional rectal tube is significantly higher than the KKU- tube by a t-score of 6.15 and p-value <0.05 (Table 3).

Table 2. The Differences of Mean, Maximum Doses between ARW, CRT and KKU-tube and Maximal Rectal Doses Calculated by using CRT ($Dmax_1$) and KKU- tubes ($Dmax_2$) and Maximal Rectal Doses Calculated by using CRT ($Dmax_1$) and KKU-tubes ($Dmax_2$)

Patient No.	Mean doses		Maximum doses		Maximal rectal doses	
	$Dmean_{0-1}$ (cGy)	$Dmean_{0-2}$ (cGy)	$Dmax_{0-1}$ (cGy)	$Dmax_{0-2}$ (cGy)	$Dmax_1$ (cGy)	$Dmax_2$ (cGy)
1	153.95	23.78	144.05	16.30	558.75	532.95
2	117.20	80.24	120.25	110.10	481.49	595.71
3	63.11	15.53	70.55	27.10	244.23	426.98
4	55.07	41.55	54.70	42.15	390.56	373.35
5	65.93	28.10	38.75	22.95	321.37	382.34
6	119.92	59.58	103.15	37.65	456.30	489.65
7	107.27	58.08	130.75	24.05	404.58	358.08
8	96.45	51.73	90.70	36.70	512.60	496.65
9	132.35	28.66	145.75	32.95	443.23	420.25
10	157.04	35.43	179.65	32.95	484.48	420.04
11	97.82	12.20	225.45	21.30	370.98	330.36
12	63.23	35.16	96.50	13.00	365.73	315.31
13	84.96	23.15	85.00	27.00	457.15	463.49
14	121.70	42.05	93.85	22.95	386.49	479.10
15	43.05	42.51	244.60	18.60	332.38	494.92
16	64.06	18.31	62.95	32.10	373.48	361.00
17	76.13	35.43	47.40	18.65	563.50	414.76
18	66.89	12.20	166.20	33.20	242.00	257.68
19	123.22	41.08	165.65	29.25	498.09	440.21
20	92.23	18.50	117.70	19.45	448.66	238.92
21	38.70	36.78	46.55	19.60	248.72	253.34
22	61.08	50.48	69.70	27.30	367.18	442.00
23	76.11	25.64	101.00	23.45	501.90	491.89
24	45.93	18.50	44.50	18.75	278.47	397.17
25	14.83	18.28	3.20	32.60	299.68	421.65
26	27.08	39.68	24.50	56.60	390.21	545.10
27	52.40	21.65	81.10	24.30	355.78	334.16
28	97.60	20.01	71.30	28.40	361.31	415.50
29	43.20	16.58	73.10	3.10	275.86	413.78
30	41.26	23.46	48.30	16.30	413.12	523.00
31	57.88	20.85	70.50	23.20	350.73	385.51
32	108.76	24.61	115.60	26.50	483.48	428.83

*Dmean0=mean dose at ARW, Dmean1=mean dose at CRT, Dmean2=mean dose at anterior KKU- tube, Dmax0=maximal dose at ARW, Dmax1= maximal dose at CRT, Dmax 2= maximal dose at anterior KKU-tube

Discussion

At present, radiotherapy with or without concurrent chemotherapy remains the most effective primary treatment of locally advanced uterine cervical cancer. Combined EBRT and ICBT is the cornerstone of radiotherapy for cervical cancer. ICBT is usually used for boosting the radiation dose to gross residual tumors at the cervix, paracervical and intrauterine tissues for increasing tumor control. When the radiation dose to the tumor is increased, the dose to adjacent normal organs will also increase and could lead to radiation complications. To minimize the radiation dose to adjacent organs, i.e. rectum and bladder, the proper techniques and doses must

Table 3. Comparison between CRT and KKU-tubes in Terms of Mean Underestimation of Rectal Dose, Mean Actual Rectal Doses, Average Maximum Dose Differences from ARW and Mean Pain Scores from Both Types of Rectal Tubes

Rectal marker		Mean	Mean diff.	95% CI of mean diff.		t-score	p value
Mean underestimation of rectal dose(cGy)	CRT	80.55	49.73	42.32	57.13	13.25	0.00
	KKU-tube	30.82					
Mean actual rectal doses(cGy)	CRT	398.76	-11.89	-25.78	2.00	-1.69	0.09
	KKU-tube	410.64					
Average maximum dose differences(cGy)	CRT	103.56	75.27	55.23	95.30	7.55	0.00
	KKU-tube	28.29					
Pain score caused by both types of rectal tubes(cGy)	CRT	2.23	0.69	0.46	0.92	6.16	0.00
	KKU-tube	1.55					

be used. Meanwhile, accurate references for evaluating and monitoring doses to organs at risk is also important.

In general, the standard method for regulating the radiation dose during intracavitary brachytherapy is based on ICRU 38. This method was performed by packing contrast-soaked gauze into the vagina. Then, orthogonal X-ray films of pelvis were taken. The reference points of the rectal wall were determined by adding 0.5 cm. from the posterior vaginal wall as seen in the contrast gauze in vagina at the level of uterine cervix. In spite of this methodology, the reference points of this method are still not the exact landmarks of rectal wall.

There have been many methods to locate the landmarks of the rectal wall such as rectal wires, rectal tubes covering an air containing contrast balloon or a rectal probe. In the study from the Institute of Oncology Sremska Kamenica of Yugoslavia (Baucal et al., 2002), they used a flexible plastic tube with the distal end covered by a balloon which was impregnated with a barium salt emulsion for visualization of the rectum on radiographs. The balloon filled with 10 to 20 cm3 of air was inserted into rectum to make the balloon close to rectal wall representing the landmarks of rectal wall. This method was significantly different from ICRU 38 technique by 15.3%. The method of the rural center of Maharashtra (Shrivastava et al., 2009) was compared to the ICRU 38 technique with a rectal tube containing opaque wires. They have found that the radiation doses measured by this rectal tube were significantly lower than ICRU 38 (p-value 0.002).

The present study has shown that the KKU- tube is significantly more accurate and underestimates the rectal dose less than the CRT. In this study, the rectal walls coated by barium contrast media were considered to be the actual ARW. By this method, the gap between rectal wall and rectal markers can be visualized on the radiographs quite clearly.

Computed tomography (CT) and magnetic resonance imaging (MRI) are now widely used for 3D brachytherapy treatment planning but these techniques are generally not available in developing countries. 2D radiograph-based planning is now still used by 43% of USA and 89% of Canadian institutions (Pearce et al., 2009; Viswanathan and Erickson, 2010). Meanwhile, 2D brachytherapy treatment planning is mainly used in Srinagarind hospital for reasons of more simplicity and low cost. Nevertheless, the standard commercialized rectal tubes for ICBT are also expensive and not available in Thailand. The KKU-model rectal tube is an easily producible, applicable and reliable instrument as a reference for evaluating the rectal doses during ICBT of cervical cancer and these tubes have not had significant negative effects on actual rectal doses as compared to CRT.

In conclusions, the KKU-model rectal tube is a more accurate and reliable reference for evaluating the rectal dose than CRT without negative effects to the patients. Other advantages of KKU-tube are that they are generally available, easily produced, of a low cost and suitable for clinical use, especially for developing countries.

Acknowledgements

The authors would like to thank Dr.Vorachai Tangvoraphonkchai for his kind permission in searching patients' data for this study and express gratitude to Miss Jitjira Chaireatthe and the Clinical Epidemiology Unit for contribution of useful data and statistical analysis. Above all, we are extremely grateful to Emeritus Professor Dr. James A Will, University of Wisconsin, Madison, Wisconsin for his valuable comments and critical review of the manuscript.

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