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Original Articles/นิพนธ์ต้นฉบับ

Radiation Dosimetry in Non-Hodgkin's B-Cell Lymphoma Patients Treated with ^{131}I-Rituximab Radioimmunotherapy

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Abstract

Objective: The aim of this study was to calculate a therapeutic dose of ^{131}I-Rituximab after a tracer patient-specific dosimetry based on whole body absorbed dose of 0.75 Gy.

Methods: Eight patients (mean ± S.D. age, 59.0 ± 11.6 years) were given initial tracer activity of ^{131}I-Rituximab intravenously. Whole body images at 10 minutes, 3 days and 6 days were used to generate the Time-activity curve (TAC). TAC was fitted by plotting Log_{10} of the percentage administered activity remaining with time of scan and was used for calculation of the effective half-life, residence time and therapeutic dose. The organs dose was calculated by MIRDOSE 3.1 software.

Results: The mean effective half-life was 145.7 ± 13.4 hours, whereas the residence time was 210.3 ± 19.4 hours. The mean therapeutic dose was 1.16 ± 0.16 GBq. The mean absorbed dose to liver, lungs, ovaries, red marrow, testes and total body was 0.58 ± 0.05, 0.54 ± 0.05, 0.63 ± 0.06, 0.56 ± 0.05, 0.53 ± 0.05 and 0.54 ± 0.06 mGy/MBq, respectively.

Conclusions: The whole body radiation dose using a patient-specific tracer dose calculation based on whole body absorbed dose of 0.75 Gy was appropriate for therapeutic dose calculation in Radioimmunotherapy (RIT) patient.

Keywords: I-131-Rituximab, Radioimmunotherapy, Non-Hodgkin's Lymphoma, Red marrow dose, Absorbed dose

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Introduction

Radiolabeled anti-CD20 monoclonal antibody (mAb) studies have recommended as a Radioimmunotherapy (RIT) for innovative treatment of non-Hodgkin's Lymphoma (NHL). It is a systemic treatment using a mAb labeled with a radionuclide to deliver a toxic level of radiation to the disease sites. The Food and Drug Administration (FDA) has approved ^{90}Yitium-Ibritumomab tiuxetan (Zevalin®) anti-B-cell NHL mAb as the first commercial available radiolabeled antibody of cancer therapy. Only a few years after that, ^{131}Iodine-Tositomomab (Baxxar®) was introduced into clinical practice[1, 2]. Thereafter, many clinical trials have published the efficacy of RIT treatment in B-cell NHLs[3-6]. However, Zevalin® and Baxaar® are expensive and not available in Thailand. Moreover, the Human Anti-mouse Antibody (HAMA) reaction may be induced to patients by the second treatment and may not be safe to patients[2, 7]. For these reasons, an alternative treatment using Rituximab, which is a standard chemotherapy, can be used to labeled with radioiodine (^{131}Iodine-Rituximab) for treatment of relapsed or refractory indolent NHLs. Many publication of Turner J.H, et al.[3, 5, 6, 8], they proved that RIT is a safe, effective treatment of low-grade lymphoma and increase overall survival and offer for routine clinical application.

The basic goal of RIT is to administer the maximum treatment dose that would deliver optimal radiation absorbed dose to tumor tissue with minimal or acceptable toxicity to critical organs. Damage to living tissues from radiation-absorbed dose is then a limitation of therapeutic applications. The principal side effect of RIT treatment is bone marrow suppressions, especially thrombocytopenia and leukopenia[9-11]. Contribution of radiation-absorbed dose to bone marrow should not exceed 2 Gy, which is equivalent to 0.75 Gy of whole body absorbed dose[3-5]. Then, evaluation of bone marrow uptake according to series of whole body imaging technique before treatment with a diagnostic dose of ^{131}I-Rituximab is useful to raise therapy efficacy in the treatment of HNLs. This method is used for the treatment planning with ^{131}I-Rituximab to maximize treatment potential while avoiding bone marrow side effects. This will decrease the mortality and improve the quality of life of the patients. The study aimed to calculate a therapeutic dose of ^{131}I-Rituximab after individual tracer dosimetry study of patient based on whole body radiation absorbed dose of 0.75 Gy.

Materials and Methods

Patients

A total of 8 patients were referred by hematologic oncologists and reviewed by a nuclear medicine physician for suitability for treatment. They received verbal and written information regarding ^{131}I-Rituximab therapy. Patient information was available through medical records. From these 8 patients, 7 patients (4 men, 3 women; mean ± S.D. age, 59.0 ± 11.6 years) completed for whole body imaging and were include in the analysis; the only one patient not completed for whole body imaging and was excluded from this study. 131I-Rituximab was kindly donated by the Thailand Institute of Nuclear Technology (TINT). Meanwhile, the research project was approved by the Institutional Review Board of Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand.

The exclusion criteria were pregnancy or breast-feeding, the administration of chemotherapy or radiotherapy within 6 weeks and platelets less than 100,000 cells/cm^3. The patient generally stared taking Saturated Solution of Potassium Iodide (SSKI), usually 10 drops per day (1 day before the study and this was continue for 21 days). SSKI was used to block the uptake of I-131 by the thyroid.

Whole Body Imaging

An initial tracer activity of ^{131}I-Rituximab (185 MBq) was injected intravenously after an infusion of unlabeled Rituximab (375 mg/cm^2) about 2 to 4 hours. The whole body imaging with 3 minutes per step bed position was performed in each individual patient with a gamma camera (Hawkeye 4 SPECT/CT scanner, GE Healthcare) at the specific time point of 10 minutes, 3 days and 6 days after injection, respectively[12]. The background count was performed with the same protocol of whole body imaging but used 60 second per step bed position. For each patient, all imaging was performed by the same position and distance between the collimator and the patient. Imaging was performed using high energy general propose collimator (HEGP collimator) with an energy window of 20 % of 364 keV (I-131). This acquired a whole body scan using a 256 × 1024 matrix with a zoom of 1.

Dosimetry

The whole body uptake of ^{131}I-Rituximab was obtained by drawing the region of interest (ROI) using the Xeleris® software (GE Healthcare). Anterior and posterior counts were converted to geometric mean counts, corrected for background and used in further analysis for dosimetry. Then, the whole body TAC was fitted by plotting Log_{10} of the percentage administered activity remaining with time of scan on a linear-linear graph. The effective half-life and residence time was calculated from TAC. The therapeutic dose of ^{131}I-Rituximab was calculated to deliver a whole-body radiation-absorbed dose of 0.75 Gy according to the standard operating procedure for prospective individulised dosimetry ^{131}I-Rituximab RIT of NHL of Calais P.J. and Turner J.H.[12]. The therapeutic activity can be calculated from equation 1[13, 14].

$$\text{Therapeutic dose (MBq)} = \frac{\text{Activity hours (MBq.h)}}{\text{Residence time (h)}} \times \frac{\text{Desired Total Body dose (Gy)}}{0.75\ \text{(Gy)}}$$

Eq.1

In order to calculate the therapeutic activity (Equation 1), there were two dosimetric parameters, which was necessary to calculated.

1) Activity hours (MBq.hr), it was dependent on the properties of the radionuclide and the patient's effective mass, which was determined on the basis of the patient's sex and patient's height. The effective mass (kg) calculated from the formula of 65.76 + [1.452 × (patient height (cm)-152)] and 62.34 + [1.247 × (patient height (cm)-152)] for male and female, respectively[12, 14]. Based upon the absorbed dose calculation and assuming a simplified ellipsoidal volume for the patient and a heterogeneous distribution of the radioiodinated antibody in the patient, the Activity hours my be derived from the simplified and semi-empirical formula:

$$\text{Activity hours}_{(\text{MBq.hr})} = (3624.59 \times \text{Weight}_{\text{kg}}) + 29283.65$$

Eq. 2

If the patient's effective mass was less than the patient's actual weight, then the effective mass was used to determine the Activity hours. However if the patient's actual weight was less than the calculated effective mass, then the patient's actual weight was used to determine the Activity hours[12].

2) Residence time, we plotted the percent of administered tracer activity of ^{131}I-Rituximab versus time on a linear-linear graph using the trend line function and display equation on graph with Microsoft Excel program. The slope of line obtained from the equation

(Figure 1). The residence time was calculated from [$Log_{10}(1/e) = -0.4343$] divided by slope of curve.

The absorbed dose per unit of the administered activity, was determined from the calculated total body residence time as input values to the software MIRDOSE 3.1[15] according to equation for absorbed dose in the Medical Internal Radiation Dose (MIRD system) Committee, given as[16];

$$D = \tilde{A}S \qquad \text{Eq. 3}$$

Where D is absorbed dose (rad or Gy), $\tilde{A}$ is cumulated activity (μCi-hr or MBq-sec) and S is absorbed dose per unit activity (rad/μCi-hr or mGy/MBq-sec)

Results

Figure 1 show the relationship between Log_{10} of the percentage administered activity remaining with time of scan on a linear-linear graph.

Table 1 show the equation of the relationship between Log_{10} of the percentage administered activity remaining with time of scan on a linear-linear graph and the body residence time calculated from the patients.

Table 2 show the effective half life, residence time and treatment dose obtained from the whole body ^{131}I-Rituximab clearance.

Table 3 show the absorbed doses per unit of administered activity of ^{131}I-Rituximab from whole body source organ (mGy/MBq).

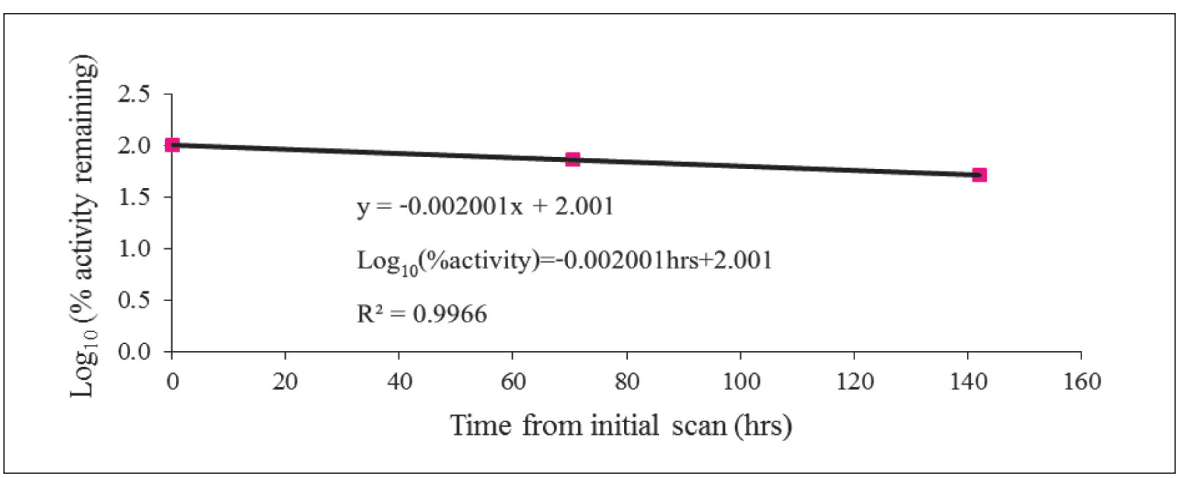

Figure 1 *Total body residence time calculation.*

Table 1 Total body residence time calculated after tracer administration from patients.

Patient number	Equation	R^2	Residence time (hr)
Pt.1	y=-0.002001x+2.001	0.99	217.04
Pt.2	y=-0.001851x+2.001	0.99	234.63
Pt.3	y=-0.002135x+2.001	0.99	141.00
Pt.4	y=-0.002101x+2.001	0.99	143.28
Pt.5	y=-0.001858x+2.001	0.96	162.02
Pt.6	y=-0.002359x+2.001	0.99	127.61
Pt.7	y=-0.002256x+2.001	0.99	133.44

Table 2 Dosimetric parameters obtained from whole body ^{131}I-Rituximab clearance.

Patient number	Effective half-life (hr)	Residence time (hr)	Treatment dose (GBq)
Pt.1	150.4	217.0	1.19
Pt.2	162.6	234.6	1.10
Pt.3	141.0	203.4	1.25
Pt.4	143.3	206.7	1.34
Pt.5	162.0	233.7	0.85
Pt.6	127.6	184.1	1.25
Pt.7	133.4	192.5	1.11
Mean ± S.D.	145.7 ± 13.4	210.3 ± 19.4	1.16 ± 0.16

Table 3 Absorbed doses per unit of administered activity of ^{131}I-Rituximab from whole body source organ (mGy/MBq).

Target organ	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
Adrenal	6.65E-01	5.24E-01	5.48E-01	5.88E-01	6.18E-01	6.68E-01	5.79E-01
Brain	5.57E-01	4.39E-01	4.59E-01	4.93E-01	5.17E-01	5.59E-01	4.85E-01
Breasts	5.25E-01	4.14E-01	4.33E-01	4.64E-01	4.88E-01	5.27E-01	4.57E-01
Gallbladder wall	6.88E-01	5.42E-01	5.67E-01	6.09E-01	6.39E-01	6.91E-01	5.99E-01
LLI wall	6.78E-01	5.34E-01	5.59E-01	6.00E-01	6.30E-01	6.81E-01	5.90E-01
Small intestine	6.89E-01	5.42E-01	5.67E-01	6.09E-01	6.39E-01	6.91E-01	5.99E-01
Stomach	6.54E-01	5.15E-01	5.38E-01	5.78E-01	6.01E-01	6.56E-01	5.69E-01
ULI wall	6.78E-01	5.34E-01	5.59E-01	6.00E-01	6.30E-01	6.81E-01	5.90E-01
Heart wall	6.51E-01	5.13E-01	5.36E-01	5.76E-01	6.04E-01	6.53E-01	5.67E-01
Kidneys	6.40E-01	5.04E-01	5.24E-01	5.66E-01	5.95E-01	6.43E-01	5.57E-01
Liver	6.41E-01	5.05E-01	5.28E-01	5.67E-01	5.95E-01	6.43E-01	5.58E-01
Lungs	6.00E-01	4.73E-01	4.94E-01	5.31E-01	5.57E-01	6.02E-01	5.22E-01
Muscle	5.91E-01	4.65E-01	4.86E-01	5.22E-01	5.48E-01	5.93E-01	5.14E-01
Ovaries	6.95E-01	5.48E-01	5.73E-01	6.15E-01	6.46E-01	6.98E-01	6.05E-01
Pancreas	6.91E-01	5.44E-01	5.69E-01	6.11E-01	6.41E-01	6.93E-01	6.01E-01
Red marrow	6.22E-01	4.90E-01	5.12E-01	5.50E-01	5.77E-01	6.24E-01	5.41E-01
Bone surface	6.83E-01	5.38E-01	5.63E-01	6.04E-01	6.35E-01	6.86E-01	5.95E-01
Skin	5.04E-01	3.97E-01	4.15E-01	4.46E-01	4.68E-01	5.06E-01	4.39E-01
Spleen	6.41E-01	5.05E-01	5.28E-01	5.67E-01	5.95E-01	6.43E-01	5.58E-01
Testes	5.90E-01	4.65E-01	4.86E-01	5.22E-01	5.48E-01	5.93E-01	5.14E-01
Thymus	6.15E-01	4.85E-01	5.07E-01	5.44E-01	5.71E-01	6.18E-01	5.35E-01
Thyroid	6.15E-01	4.85E-01	5.07E-01	5.44E-01	5.71E-01	6.18E-01	5.35E-01
Urinary bladder	6.71E-01	5.29E-01	5.53E-01	5.93E-01	6.23E-01	6.74E-01	5.84E-01
Uterus	7.01E-01	5.52E-01	5.77E-01	6.20E-01	6.50E-01	7.03E-01	6.10E-01
Total body	5.95E-01	4.69E-01	4.90E-01	5.26E-01	5.53E-01	5.97E-01	5.18E-01

Disscusion

The effective half-life obtained from the TAC ranged from 127.6 to 162.6 hours, with a mean ± S.D. of 145.7 ± 13.4 hours. The plot of TAC should be a straight line, or very nearly so. If it is not, the data needs to be verified. Common causes of error are: time and data entered incorrectly; counts measured incorrectly; incorrect gamma camera settings (e.g., one scan was at a different speed, window setting etc.); significant change in patient lifestyle during dosimetry examination period (exercise, work, diet, quantity of fluid drunk etc.).

The mean ± S.D. of the residence time was 210.3 ± 19.4 (184.1 to 234.6) hours (Table 1). However, the residence time is a characteristic of individual patient, which is always shorter than the physical half-life. An accurate organ residence time is an essential part of treatment planning dosimetry.

The administered therapeutic activity of ^{131}I-Rituximab ranged from 0.85 to 1.34 GBq (mean, 1.16 ± 0.16 GBq) (Table 2). Our result was similar to that of the study by Calais et al.[17] They evaluated the T_{eff} from the tracer study of ^{131}I-Rituximab according to the prescribed dose of 0.75 Gy to the whole body ranging from 27.1 to 152.2 hours, with a mean of 96.4 hours and S.D. of 18.14 hours. The therapeutic activities of ^{131}I-Rituximab ranged between 1 and 4.5 GBq (mean, 2.3 GBq).

The average absorbed doses to total body (0.54 ± 0.06 mGy/MBq) were calculated by the MIRDOSE3.1 computer software (Table 3). The absorbed dose (mean ± S.D.) in red marrow, liver, lungs, ovaries and testes was 0.56 ± 0.05, 0.58 ± 0.05, 0.54 ± 0.05, 0.63 ± 0.06, and 0.53 ± 0.05 mGy/MBq, respectively. The mean effective dose was 0.57 ± 0.06 mSv/MBq.

Conclusions

The whole body dose using a patient-specific dose calculation based on the measured total-body residence time and effective half-lives was appropriate for therapeutic dose calculation and a formed to be good predictor for potential marrow toxicity. We demonstrated the first case report of ^{131}I-Rituximab in Thailand[18]. We found that ^{131}I-Rituximab gave an impressive treatment response as observed in the present patient. However, since this technique is first introduced in Thailand, further investigations with more patients are required to evaluate its greater impact.

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Original Articles/นิพนธ์ต้นฉบับ

การคำนวณปริมาณรังสีในผู้ป่วยมะเร็งต่อมน้ำเหลืองนอนฮอดจ์กินชนิดบีเซลล์ที่ได้รับการรักษาด้วยสารเภสัชรังสี Iodine-131-Rituximab

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บทคัดย่อ

วัตถุประสงค์: เพื่อคำนวณปริมาณความแรงรังสีของสารเภสัชรังสี ^{131}I-rituximab ในการรักษาผู้ป่วยมะเร็งต่อมน้ำเหลืองนอนฮอดจ์กินชนิดบีเซลล์ โดยอ้างอิงปริมาณรังสีดูดกลืนที่ร่างกายผู้ป่วยได้รับไม่เกิน 0.75 Gy

วิธีการศึกษา: หลังจากการใช้รังสีปริมาณน้อยสำหรับการวินิจฉัย และใช้ในการถ่ายภาพรังสีผู้ป่วยแต่ละราย โดยผู้ป่วยทั้งหมดจำนวน 8 ราย (อายุ 59.0 ± 11.6 ปี) ได้รับปริมาณความแรงรังสี 185 MBq ของสารเภสัชรังสี ^{131}I-rituximab ฉีดเข้าทางหลอดเลือดดำ จากนั้นถ่ายภาพรังสีทั้งตัวด้านหน้าและด้านหลังของผู้ป่วยที่ 10 นาที 3 วัน และ 6 วัน ตามลำดับ หลังจากผู้ป่วยได้รับสารเภสัชรังสี จากนั้นทำการสร้างกราฟการลดลงของปริมาณสารเภสัชรังสีในร่างกายผู้ป่วยตามเวลาที่ถ่ายภาพรังสี ข้อมูลที่ได้จากกราฟดังกล่าวใช้ในการประเมินครึ่งชีวิตยังผล ระยะเวลาที่สารเภสัชรังสีสะสมอยู่ในร่างกาย และคำนวณความแรงรังสีของสารเภสัชรังสี ^{131}I-rituximab สำหรับใช้รักษาผู้ป่วยมะเร็งต่อมน้ำเหลืองนอนฮอดจ์กินชนิดบีเซลล์ รวมถึงคำนวณปริมาณรังสีดูดกลืนที่อวัยวะต่าง ๆ ของผู้ป่วยด้วยโปรแกรม MIRDOSE 3.1

ผลการศึกษา: ค่าครึ่งชีวิตยังผล และระยะเวลาที่สารเภสัชรังสีสะสมอยู่ในร่างกายมีค่าเฉลี่ยเป็น 145.7 ± 13.4 ชั่วโมง และ 210.3 ± 19.4 ชั่วโมง ตามลำดับ ความแรงรังสีของสารเภสัชรังสี ^{131}I-rituximab สำหรับใช้รักษาผู้ป่วยมะเร็งต่อมน้ำเหลืองนอนฮอดจ์กินชนิดบีเซลล์มีค่าเฉลี่ยเป็น 1.16 ± 0.16 GBq ค่าเฉลี่ยปริมาณรังสีดูดกลืน ที่ตับ ปอด รังไข่ ไขกระดูกแดง, อัณฑะ และทั่วร่างกายมีค่าเป็น 0.58 ± 0.05, 0.54 ± 0.05, 0.63 ± 0.06, 0.56 ± 0.05, 0.53 ± 0.05 และ 0.54 ± 0.06 mGy/MBq ตามลำดับ

สรุป: ปริมาณรังสีที่ผู้ป่วยได้รับโดยใช้ข้อมูลของผู้ป่วยในแต่ละราย โดยอ้างอิงปริมาณรังสีดูดกลืนที่ผู้ป่วยทั้งตัวได้รับไม่เกิน 0.75 Gy นั้น มีความเหมาะสมสำหรับการคำนวณปริมาณความแรงของสารเภสัชรังสี ^{131}I-rituximab ในการรักษาผู้ป่วยเพื่อช่วยลดอัตราการตายและปรับปรุงคุณภาพชีวิตของผู้ป่วย

คำสำคัญ: I-131-Rituximab, Radioimmunotherapy, Non-Hodgkin's Lymphoma, Red marrow dose, Absorbed dose

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