Table 1 Annual numbers of cancer patients treated with radiation, linac, and by radiation oncology professionals. Plus, patients' load/personnel according to stratification of institution by FTE radiation oncologist

	全施設(712)		A施設層(274)※2		B施設層(438)※3	
	1施設平均	総数	1施設平均	総数	1施設平均	総数
実患者数	268.5	191,173	444.2	121,711	158.6	69,462
新規患者数	219.5	156,318	361.2	98,968	130.9	57,350
リニアック台数	1.1	765	1.3	368	0.9	397
放射線治療担当医(FTE)※1	1.1	774.5	2.2	609	0.4	165.5
JASTRO認定医(常勤)	0.6	426	1.3	350	0.3	76
実患者数/FTE放射線治療担当医1名	246.8		199.9		158.6※4	
新規患者数/FTE放射線治療担当医1名	201.8		162.5		130.9※4	
放射線治療担当技師数(専任)	1.5	1,061.7	2.5	686.1	0.9	375.6
放射線治療担当技師数(兼任)	0.8	572.8	0.8	223.2	0.8	349.6
放射線治療担当技師数(専任+兼任)	2.3	1,634.5	3.3	909.3	1.7	725.2
実患者数/放射線治療担当技師1名(専任+兼任)	117.0		133.9		95.8	
新規患者数/放射線治療担当技師1名(専任+兼任)	95.6		108.8		79.1	
放射線治療担当技師数(専任+兼任)/リニアック1台	2.1		2.5		1.8	
医学物理士数(常勤)	0.2	117	0.3	86	0.1	31
医学物理士数(非常勤)	0.04	30.1	0.08	23.1	0.02	7
医学物理士数(常勤+非常勤)	0.2	147.1	0.4	109.1	0.1	38
実患者数/医学物理士1名(常勤+非常勤)	1,299.6		1,115.6		1,827.9	
新規患者数/医学物理士1名(常勤+非常勤)	1,062.7		907.1		1,509.2	
品質管理士数(常勤)	0.4	256.8	0.6	164.5	0.2	92.3
品質管理士数(非常勤)	0.02	13.0	0.03	9	0.01	4
品質管理士数(常勤+非常勤)	0.4	269.8	0.6	173.5	0.2	96.3
実患者数/品質管理士1名(常勤+非常勤)	708.6		701.5		721.3	
新規患者数/品質管理士1名(常勤+非常勤)	579.4		570.4		595.5	
品質管理士数(常勤+非常勤)/リニアック1台	0.4		0.5		0.2	

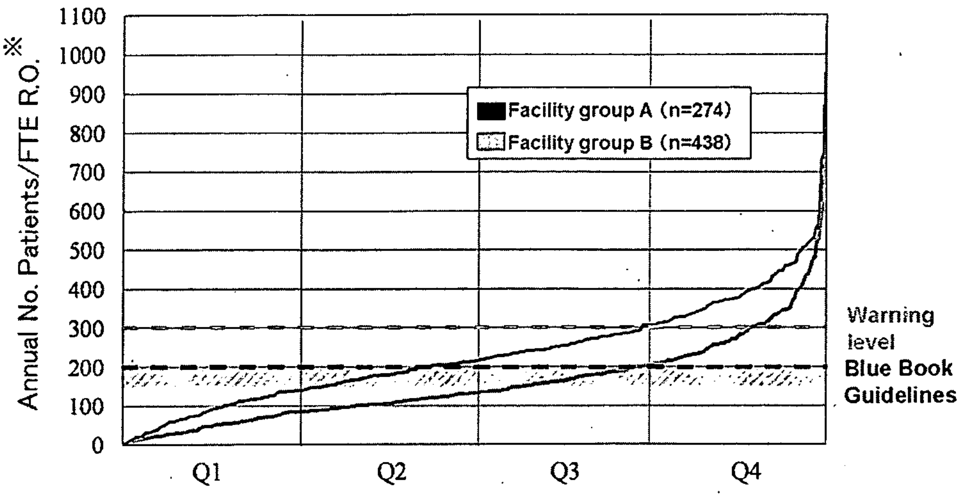
※1 FTE (full time equivalent)：週40時間放射線治療専任業務に換算し直した実質的マンパワー
※2 A施設層：FTE≧1の施設層
※3 B施設層：FTE＜1の施設層
※4 FTE＜1の施設の場合はFTE=1として換算
2005年放射線治療実施施設を735施設と推測した場合の推定実患者数：約19万8,000人
2005年放射線治療実施施設を735施設と推測した場合の推定新患者数：約16万2,000人

放射線治療担当医

1施設平均のFTE放射線治療担当医は，A施設2.2人，B施設0.5人であった．常勤のJASTRO認定医は，A施設199人，B施設35人であった．年間実患者数/FTE放射線治療担当医は264人で，A施設では平均235人，B施設では上記1と同様にFTE=1とした場合，202人であった．B施設では既述のように，平均0.5 FTE人で治療している．これらの患者数負荷について，すべての施設の値の分布をみると(Fig. 3)，A施設の70％は日米ブルーブックの基準[12), 13)]である200人/FTE放射線腫瘍医以上の患者を治療していた．上位30％の施設では改善警告値である300名を超えて治療していた．B施設の上位15％の施設では，改善警告値300名を超えて治療していた．上記1と同様に注意すべきは，平均0.5 FTE人の放射線治療担当医なので，患者の診療にかかわれる時間がA施設のそれより実質半数である点である．

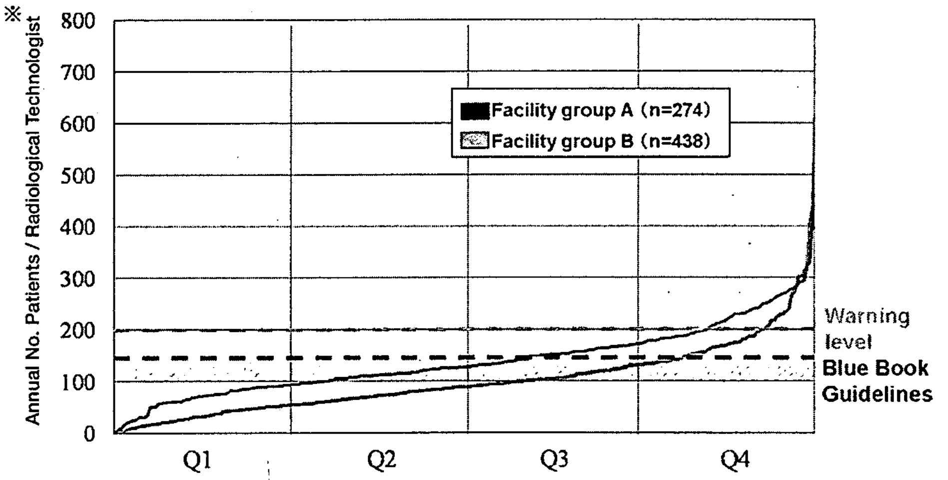
放射線治療担当技師

1施設平均の放射線治療担当技師(専任+兼任)は，A施設3.6人，B施設1.7人であった．年間実患者数/放射線治療担当技師は134人で，A施設では142人，B施設では114人であった．linac 1台当たりの放射線治療担当技師数(専任+兼任)は2.3人で，A施設では2.5人，B施設では1.8人であった．同様に，これらをすべての施設で分布をみると(Fig. 4)，A施設は日本版ブルーブックの基準[12)]である100～150人/放射線治療担当技師の範囲以上の患者を75％以上の施設で治療していた．上位20％弱の施設では，改善警告値であ



※FTE<1 の施設はFTE=1 として算出

Fig. 1 Distribution of annual patient load/FTE radiation oncologist in radiation oncology facility. Horizontal axis represents facilities arranged in order of increasing value of annual number of patients/FTE radiation oncologist within facilities.
Q1: 0-25%, Q2: 26-50%, Q3: 51-75%, Q4: 76-100%.



※技師数が 1 未満の施設（8 施設）は，患者負荷の過大評価を避けるため，技師数 1 名として換算．うち 2 施設は技師数 0（γナイフのみの施設と歯科大学病院で年間実患者数 3）

Fig. 2 Distribution of annual patient load/radiation technologist in radiation oncology facility. Horizontal axis represents facilities arranged in order of increasing value of annual number of patients/radiation technologist within facilities.
Q1: 0-25%, Q2: 26-50%, Q3: 51-75%, Q4: 76-100%.

る200人を超えて診療していた．B施設の50％以上の施設で，基準値以上の数の治療をしていた．10％の施設では改善警告値を超えていた．

医学物理士

全体の医学物理士数（常勤+非常勤）は63人であり，A施設では49人，B施設では14人であった．年間実患者数/医学物理士は1,556人であった．

品質管理士

全体の品質管理士数（常勤+非常勤）は132人であり，A施設では100人，B施設では32人であった．年間実患者数/品質管理士は744人であった．

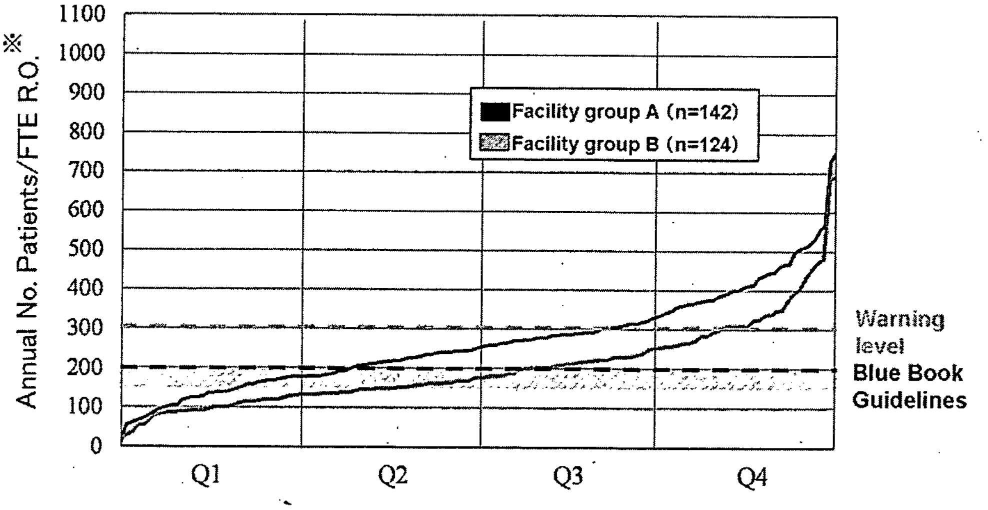
3．施設層（放射線治療担当医のマンパワー）別のlinac機能およびCT simulator装備分布

Table 3 に，施設規模別，すなわち放射線治療担当医のマンパワー別（FTE≥1 対 <1）のlinacの機能およびCT simulator

Table 2　Annual numbers of cancer patients treated with radiation, linac, by radiation oncology personnel. Plus, patients' load/personnel in designated cancer care hospitals according to stratification of institution by FTE radiation oncologist

	全施設(266)※1		A施設層(142)		B施設層(124)	
	1施設平均	総数	1施設平均	総数	1施設平均	総数
実患者数	369.2	98,201	514.9	73,110	202.3	25,091
新規患者数	298.5	79,408	412.6	58,594	167.9	20,814
リニアック台数	1.2	325	1.4	204	1.0	121
放射線治療担当医(FTE)	1.4	372.5	2.2	311.1	0.5	61.4
JASTRO認定医(常勤)	0.9	234	1.4	199	0.3	35
実患者数/FTE放射線治療担当医1名	263.6		235.0		202.3	
新規患者数/FTE放射線治療担当医1名	213.2		188.3		167.9	
放射線治療担当技師数(専任)	1.9	518.5	2.7	388.6	1.0	129.9
放射線治療担当技師数(兼任)	0.8	216.1	0.9	126.3	0.7	89.8
放射線治療担当技師数(専任+兼任)	2.8	734.6	3.6	514.9	1.8	219.7
実患者数/放射線治療担当技師1名(専任+兼任)	133.7		142.0		114.2	
新規患者数/放射線治療担当技師1名(専任+兼任)	108.1		113.8		94.7	
放射線治療担当技師数(専任+兼任)/リニアック1台	2.3		2.5		1.8	
医学物理士数(常勤)	0.2	49	0.3	36	0.1	13
医学物理士数(非常勤)	0.05	14.1	0.09	13.1	0.01	1
医学物理士数(常勤+非常勤)	0.2	63.1	0.3	49.1	0.1	14
実患者数/医学物理士1名(常勤+非常勤)	1,556.3		1,489.0		1,792.2	
新規患者数/医学物理士1名(常勤+非常勤)	1,258.4		1,193.4		1,486.7	
品質管理士数(常勤)	0.5	124	0.6	92	0.3	32
品質管理士数(非常勤)	0.03	8	0.06	8	0	0
品質管理士数(常勤+非常勤)	0.5	132	0.7	100	0.3	32
実患者数/品質管理士1名(常勤+非常勤)	743.9		731.1		784.1	
新規患者数/品質管理士1名(常勤+非常勤)	601.6		585.9		650.4	
品質管理士数(常勤+非常勤)/リニアック1台	0.4		0.5		0.3	

※1 がん診療連携拠点病院（国立がんセンター中央病院・東病院含む）288施設のうち，放射線治療を行っていない，もしくは構造調査の回答がなかった22施設を除いた施設数



※FTE<1 の施設はFTE=1 として算出

Fig. 3　Distribution of annual patient load/FTE radiation oncologist in designated cancer care hospitals. Horizontal axis represents facilities arranged in order of increasing value of annual number of patients/FTE radiation oncologist within facilities.
Q1: 0-25%, Q2: 26-50%, Q3: 51-75%, Q4: 76-100%.

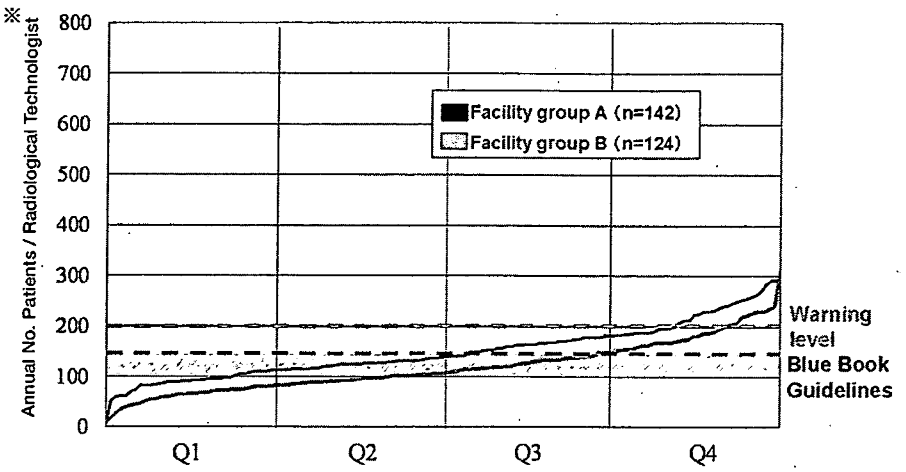


Fig. 4 Distribution of annual patient load/radiation technologist in designated cancer care hospital. Horizontal axis represents facilities arranged in order of increasing value of annual number of patients/radiation technologist within facilities.
Q1: 0-25%, Q2: 26-50%, Q3: 51-75%, Q4: 76-100%.

Table 3 Number of equipments and their functions in both nationwide and designated cancer care hospitals according to stratification of institution by FTE radiation oncologist

	全施設(%)	A施設層(%)	B施設層(%)
全国放射線治療施設全施設	712施設	274施設	438施設
Linac	657(92.3)	263(96.0)	394(90.0)
with dual energy function	451(63.3)	217(79.2)	234(53.4)
with 3DCRT function (MLC width=<1.0cm)	397(55.8)	196(71.5)	201(45.9)
with IMRT function	141(19.8)	92(33.6)	49(11.2)
CT simulator	394(55.3)	194(70.8)	200(45.7)
がん診療連携拠点病院	266施設	142施設	124施設
Linac	258(97.0)	140(98.6)	118(95.2)
with dual energy function	204(76.7)	125(88.0)	79(63.7)
with 3DCRT function (MLC width=<1.0cm)	181(68.0)	112(78.9)	69(55.6)
with IMRT function	78(29.3)	57(40.1)	21(16.9)
CT simulator	175(65.8)	107(75.4)	68(54.8)

装備の分布を示している．全国的には，dual energy機能は63%，3DCRT機能(MLC幅≤1cm)は56%，IMRT機能は20%，CT simulatorは55%に装備されていた．施設層別では，A施設ではそれぞれ79%，72%，34%，71%に装備されていた．B施設ではそれぞれ53%，46%，11%，46%に装備されていた．A施設とB施設のlinacの各機能とCT simulator設置率には，それぞれ約20%の差異が観察された．

一方，がん診療連携拠点病院[11]では，全国的にはdual energy機能は77%，3DCRT機能は68%，IMRT機能は29%，CT simulatorは66%に装備され，施設層別ではA施設ではそれぞれ88%，79%，40%，75%に，B施設ではそれぞれ64%，56%，17%，55%に装備されていた．同様に，施設層別のlinacの各機能とCT simulator設置率には，それぞれ約20%の差異が観察された．全国平均とがん診療連携拠点病院では，linac各機能とCT simulatorにはそれぞれ約10%の差異が観察された．

4．地域別の放射線治療実患者数，放射線治療担当医および放射線治療担当技師当たりの患者数負荷

Table 4に，都道府県別の人口[14]，放射線治療実患者数(新患+再患)，治療施設数，JASTRO認定医数，FTE放射線治療担当医数および1 FTE放射線治療担当医当たりの実患者数(患者負荷)，放射線治療担当技師数(常勤+非常勤)および1放射線治療担当技師当たりの実患者数(患者負荷)，医学物理士数，品質管理士数を示している．1 FTE放射線治療担当医当たりの実患者数(患者負荷)は，478人(佐賀県)から148人(群馬県)までの幅広いバリエーションが観察

Table 4 Number of patients, facilities, certified personnel, patient load/personnel according to prefecture

都道府県名	人口[19] 単位:1,000人	放射線治療実患者数:人 (人口1,000人当実患者数)	治療施設数 (1施設当人口:1,000人)	JASTRO 認定医数	FTE放射線治療担当医数 (実患者数/FTE:人)	放射線治療担当技師数 (実患者数/技師数:人)	医学物理士数 (常勤+非常勤)	品質管理士数 (常勤+非常勤)
北海道	5,628	11,852(2.1)	31(182)	25	45.6(259.9)	70.9(173.3)	6	21
青森県	1,437	1,733(1.2)	10(144)	6	9.5(182.4)	23.0(75.3)	4	7
岩手県	1,385	1,907(1.4)	9(154)	2	6.7(284.6)	16.0(127.1)	1	2
宮城県	2,360	3,955(1.7)	13(182)	6	14.4(274.3)	32.0(123.6)	3	6
秋田県	1,146	1,954(1.7)	11(104)	2	9.9(197.4)	19.0(102.8)	0	2
山形県	1,216	1,550(1.3)	8(152)	2	5.3(292.5)	12.8(121.1)	2	0
福島県	2,091	2,294(1.1)	9(232)	2	9.9(231.7)	18.0(127.4)	2	0
茨城県	2,975	3,679(1.2)	16(186)	6	18.0(204.4)	32.5(113.2)	5	3
栃木県	2,017	3,404(1.7)	10(202)	5	9.7(350.9)	31.0(109.8)	2	4
群馬県	2,024	3,571(1.8)	13(156)	17	24.1(148.2)	27.1(131.8)	2	15
埼玉県	7,054	6,135(0.9)	20(353)	15	22.0(278.9)	55.5(110.5)	4	8
千葉県	6,056	7,931(1.3)	21(288)	24	47.3(167.7)	72.3(109.8)	13	12
東京都	12,577	25,561(2.0)	70(180)	62	100.7(253.8)	223.7(114.3)	24	42
神奈川県	8,792	11,637(1.3)	37(238)	32	43.4(268.1)	105.4(110.4)	8	12
新潟県	2,431	3,536(1.5)	14(174)	6	11.6(304.8)	34.5(102.5)	3.1	1
富山県	1,112	1,990(1.8)	8(139)	4	6.0(331.7)	18.5(107.6)	1	6
石川県	1,174	1,938(1.7)	8(147)	3	5.2(372.7)	17.3(112.3)	1	2
福井県	822	1,097(1.3)	8(103)	4	6.3(174.1)	15.0(73.1)	5	4
山梨県	885	1,271(1.4)	4(221)	3	7.2(176.5)	7.0(181.6)	0	0
長野県	2,196	3,167(1.4)	14(157)	5	9.5(333.4)	26.6(119.1)	1	0
岐阜県	2,107	2,928(1.4)	11(192)	3	9.1(321.8)	20.5(142.8)	3	3
静岡県	3,792	6,977(1.8)	27(140)	10	25.0(279.0)	65.5(106.5)	4	5.5
愛知県	7,255	9,366(1.3)	37(196)	15	34.4(272.7)	78.0(120.1)	4	11
三重県	1,867	2,570(1.4)	13(144)	5	9.0(285.6)	23.5(109.4)	1	2
滋賀県	1,380	1,490(1.1)	9(153)	3	7.2(206.9)	19.0(78.4)	2	3
京都府	2,648	3,608(1.4)	13(204)	11	18.9(190.9)	31.0(116.4)	4	6
大阪府	8,817	12,885(1.5)	44(200)	29	46.4(277.7)	116.8(110.3)	9	23.3
兵庫県	5,591	8,371(1.5)	32(175)	22	38.3(218.6)	77.5(108.0)	5	12
奈良県	1,421	2,175(1.5)	8(178)	8	9.9(219.7)	25.0(87.0)	3	6
和歌山県	1,036	1,684(1.6)	9(115)	4	7.1(237.2)	19.0(88.6)	2	1
鳥取県	607	1,091(1.8)	6(101)	1	5.3(207.4)	8.0(136.4)	0	2
島根県	742	1,145(1.5)	6(124)	2	3.9(292.1)	10.0(114.5)	1	1
岡山県	1,957	2,742(1.4)	11(178)	8	10.3(266.2)	21.6(126.8)	2	5
広島県	2,877	5,496(1.9)	19(151)	18	21.7(253.9)	39.5(139.1)	3	9
山口県	1,493	2,049(1.4)	12(124)	4	8.5(241.1)	20.7(99.0)	0	3
徳島県	810	1,097(1.4)	5(162)	2	4.6(238.5)	10.0(109.7)	3	3
香川県	1,012	1,375(1.4)	10(101)	7	7.8(176.3)	13.0(105.8)	0	3
愛媛県	1,468	2,019(1.4)	10(147)	5	9.1(221.9)	18.5(109.1)	0	4
高知県	796	1,180(1.5)	6(133)	3	4.6(256.5)	9.0(131.1)	0	2
福岡県	5,050	7,925(1.6)	27(187)	17	34.0(233.1)	52.0(152.4)	5	11
佐賀県	866	1,051(1.2)	4(217)	1	2.2(477.7)	5.5(191.1)	0	0
長崎県	1,479	2,029(1.4)	7(211)	4	7.4(274.2)	14.0(144.9)	2	2
熊本県	1,842	2,562(1.4)	13(142)	4	9.4(272.6)	22.5(113.9)	1	2
大分県	1,210	1,859(1.5)	12(101)	2	5.0(371.8)	16.8(110.7)	0	0
宮崎県	1,153	1,962(1.7)	9(128)	2	6.8(288.5)	17.0(115.4)	1	1
鹿児島県	1,753	2,125(1.2)	12(146)	3	8.6(248.5)	15.0(141.7)	4	2
沖縄県	1,362	1,250(0.9)	6(227)	2	7.8(160.3)	7.5(166.7)	1	0
合計	127,768	191,173(1.5)	712(179)	426	774.5(246.8)	1634.5(117.0)	147.1	269.8

2005年放射線治療実施施設数を735施設と推測した場合の推定実患者数:約19万8,000人

Table 5 The average number of cancer patients treated with radiation and radiation oncology personnel, in institution according to patient load/FTE radiation oncologist or number of new patients.

	All facilities (n=712)	Heavy load/FTE R.O.※1 institution in group B (n=48)	Heavy load/FTE R.O.※1 institution in group A (n=72)	New patients≧800 institution in all facilities (n=19)
平均年間新規患者数	219.5	312.5	452.9	983.2
平均年間実患者数	268.5	401.5	579.4	1212.6
放射線治療担当医FTE	1.1	0.6	1.5	5.5
放射線治療担当技師数	2.3	2.2	3.5	8.4
医学物理士数	0.2	0.2	0.3	1.1
放射線治療品質管理士数	0.4	0.3	0.6	2.0

※1 Annual No. patients/FTE R.O.≧300, B施設層はFTE=1として計算

Table 6 Region and number of radiation oncology facilities according to patient load/FTE radiation oncologist or number of new patients

地域(都道府県数)	解析施設数		Heavy load/FTE R.O. institution in group B (n=48)		Heavy load/FTE R.O. institution in group A (n=72)		New patients≧800 institution in all facilities (n=19)	
北海道(1)	31	4.4%	1	2.1%	9	12.5%	3	15.8%
東北(6)	60	8.4%	5	10.4%	1	1.4%	1	5.3%
関東(8)	191	26.8%	17	35.4%	24	33.3%	9	47.4%
信越·北陸(5)	52	7.3%	6	12.5%	4	5.6%	1	5.3%
東海(4)	88	12.4%	5	10.4%	10	13.9%	2	10.5%
近畿(6)	115	16.2%	7	14.6%	12	16.7%	2	10.5%
中国(5)	54	7.6%	2	4.2%	4	5.6%	0	0.0%
四国(4)	31	4.4%	0	0.0%	1	1.4%	0	0.0%
九州・沖縄(8)	90	12.6%	5	10.4%	7	9.7%	1	5.3%
全国(47)	712※1	100%	48	100%	72	100%	19	100%

※1 2005年放射線治療実施施設数は735施設と推測され,712施設は96.9%に相当

された.1放射線治療担当技師当たりの実患者数(患者負荷)にも,191人(佐賀県)から73人(福井県)までの幅広いバリエーションがあった.

医学物理士は,東京都が24人と最も多く,次いで千葉県:13人,大阪府:9人の順であった.9県(秋田,山梨,鳥取,山口,香川,愛媛,高知,佐賀,大分)で不在であった.品質管理士は,東京都が42人と最も多く,次いで大阪府:23人,北海道:21人が多かった.7県(山形,福島,山梨,長野,佐賀,大分,沖縄)で不在であった.

5. 高負荷施設および大規模施設の分析

Table 5に,放射線治療担当医の年間患者数負荷が300名以上(日本版ブルーブック[12]改善警告値)の高負荷施設と施設当たりの新患数が800名以上の大規模施設について,スタッフ数を全体との比較のもとに示している.高負荷施設のうち,B施設層では48施設あり,放射線治療担当医は0.6 FTE人,同A施設層は72施設あり,1.5 FTE人であった.放射線治療担当技師数はそれぞれ2.2人,3.5人であった.年間平均実患者数は402人と579人であった.一方,大規模施設は19施設あり,放射線治療担当医は5.5 FTE人で,放射線治療担当技師数は8.4人であり,平均年間実患者数は1,213人であった.1 FTE放射線治療担当医当たりの患者数負荷(1212.6/5.5=220人)は日米ブルーブックガイドライン[12),13)]内に収まっていた.これらの施設の地域分布をTable 6に示している.高負荷施設のうち,B施設層のものは全体に比べ関東,信越・北陸,近畿により多く,A施設層は北海道,関東により多かった.大規模施設は北海道,関東により多かった.施設の組織区分をTable 7に示している.高負荷施設(B施設層)は,O:赤十字,済生会,企業/公社,国保/社保/共済/労災/組合/厚生連病院等とH:医療法人,医師会病院,個人病院,その他がより多くなっていた.高負荷施設(A施設層)は,G:国立がんセンター・成人病センター・地方がんセンターがより多くなっていた.一方,大規模施設は,U:大学附属病院42%とG:47%が大部分であった.

Table 8に,これらの施設の装備である治療機器と周辺機器の整備状況を示している.高負荷施設(B施設層)は全体

Table 7 Number of facilities (%) by their category according to patient load/FTE radiation oncologist or number of new patients

	施設組織区分※1						
	U	G	N	P	O	H	Total
All facilities	112	29	71	215	181	104	712
(n=712)	15.7%	4.1%	10.0%	30.2%	25.4%	14.6%	100%
Heavy load/FTE R.O.	4	2	2	10	16	14	48
institution in group B (n=48)	8.3%	4.2%	4.2%	20.8%	33.3%	29.2%	100%
Heavy load/FTE R.O.	11	11	4	18	17	11	72
institution in group A (n=72)	15.3%	15.3%	5.6%	25.0%	23.6%	15.3%	100%
New patients≧800	8	9	0	1	0	1	19
institution in all facilities (n=19)	42.1%	47.4%	0.0%	5.3%	0.0%	5.3%	100%

※1 施設組織区分
U：大学附属病院
G：国立がんセンター・成人病センター・地方がんセンター
N：独立行政法人国立病院機構（がんセンター等を除く）
P：公立（都道府県市町村立）病院（がんセンター等を除く）
O：赤十字病院，済生会病院，企業／公社病院，国保／社保／共済／労災／組合／厚生連病院等
H：医療法人，医師会病院，個人病院，その他

と比較し，外部照射装置の機能は充実しているが，Brachytherapy装置設置は遅れている．同（A施設層）は，外部照射装置の機能は全体よりやや上回っており，Brachytherapy装置は5割以上，CT simulatorは7割以上に普及していた．大規模施設では3DCRT機能9割，IMRT機能7割，Brachytherapy装置，CT simulatorは100％普及していた．linac当たりの年間実患者数負荷は，それぞれ371人，415人，501人であり，後2者で日本版ブルーブック[12), 13)]の改善警告値400人を凌駕していた．

Table 9に，これらの施設の治療計画管理料数とその難易度を全施設と比較して示している．3施設層ともに単純（1門照射，対向2門照射）が数％ずつ減少して，中間（非対向2門照射，3門照射）と複雑（4門以上の照射，運動照射，原体照射）が，わずかに増えていた．Table 10に特殊治療の施行施設数（率）を示している．腔内照射，組織内照射，前立腺ヨード治療は，高負荷施設（B施設層）で全体より低下しているが，同（A施設層）では全体の2倍以上の割合の施設で，大規模施設では4～7倍の割合の施設で施行していた．全身照射は，33％，56％，84％の施設で施行していた．定位（脳）照射は，全体では28％，それぞれ44％，56％，84％の施設で施行していた．定位（体幹部）照射は，全体では13％，それぞれ17％，29％，68％の施設で施行していた．IMRTは全体で5％，それぞれ4％，11％，53％の施設で施行していた．Table 11に，脳転移，骨転移の施行割合を示している．高負荷施設（B施設層）で，脳転移が全国平均より2倍と高くなっていた．骨転移は少なくなっていた．同（A施設層）では，脳転移がやや減少し，骨転移が多くなっていた．大規模施設では脳転移，骨転移ともに減少していた．

考　察

今回の第8次JASTRO定期構造調査結果の全体像については，第1報にて詳細を報告した．その分析で，放射線治療患者数の伸びが当初の予想より少し頭打ちになっている事実が指摘された．linacの各機能やCT simulatorに代表されるように，装備はより良いものに改善されていた．しかし，放射線治療担当医数の伸びは十分でなかった．1 FTE放射線治療担当医が扱う年間がん患者実数（新患+再患）は247人であり，米国および日本の基準[12), 13)]200名を凌駕していた．この放射線治療担当医数の不足が放射線治療技術の複雑化，高度化に加えて，支援スタッフ寡少のわが国の治療現場を疲弊させる原因になっていないか危惧された．今後の放射線腫瘍学分野の発展のためには，放射線腫瘍医ならびに支援スタッフを増やすことが最優先課題である．本報告では，わが国の現状を構造調査結果にもとづいて正しく把握し，各施設が人員増に向けて，病院事務や行政との交渉に利用可能な数値データを提供することを目的としている．

国全体で62％の放射線治療施設（B施設）において，FTE≥1名の放射線治療担当医が確保されていない．これらの施設では，2005年で年間平均150人の患者数を治療しているので，日米ブルーブックの基準200人からは，1人の放射線治療担当医の配置は必須とは言えないかもしれない．しかし，今後の急速な患者数の増加を吸収するために重要な役割を担うのは，この規模の施設であろう．したがって，この施設にFTE≥1名の常勤放射線治療医を配置することは重要である．この規模の施設における放射線治療の適用率が長らく常勤放射線治療担当医不在のために低く，国

Table 8 Number of equipments and their function in radiation oncology facilities according to patient load/FTE radiation oncologist or number of new patients

治療機器（機能）と周辺機器	All facilities (n=712)		Heavy load/FTE R.O. institution in group B (n=48)		Heavy load/FTE R.O. institution in group A (n=72)		New patients≧800 institution in all facilities (n=19)	
Linac	765		39		96		46	
with dual energy function	498	65.1%※1	30	76.9%※1	70	72.9%※1	33	71.7%※1
with 3DCRT function (MLC width=<1.0cm)	462	60.4%※1	28	71.8%※1	65	67.7%※1	41	89.1%※1
with IMRT function	170	22.2%※1	10	25.6%※1	27	28.1%※1	32	69.6%※1
Annual No. patients/Linac	234.6※2		371.2※2		415.1※2		500.9	
Betatron	0		0		0		0	
Telecobalt (actual use)	34 (11)		1 (1)		4 (2)		3 (3)	
Gamma knife	48		14		7		3	
Other accelerator	12		0		2		3	
Co-60 RALS (actual use)	74 (64)	10.4%※3 (9.0%)	5 (3)	10.4%※3 (6.3%)	15 (14)	20.8%※3 (19.4%)	3 (3)	15.8%※3 (15.8%)
Ir-192 RALS (actual use)	123 (119)	17.1%※3 (16.6%)	3 (3)	6.3%※3 (6.3%)	27 (27)	37.5%※3 (37.5%)	17 (17)	89.5%※3 (89.5%)
X-ray simulator	502	69.7%※3	27 (27)	56.3%※3	53	70.8%※3	18	89.5%※3
CT-simulator	407	55.3%※3	27 (27)	56.3%※3	55	73.6%※3	22	100%※3
RTP computer (2 or more)	940 (146)		56 (45)		121 (22)		89 (18)	

※1 linacの台数に対する機能の割合

※2 linacが設置されていない施設を除いたデータから算出（n=657, 69, 37）

※3 機器を保有している施設の割合（機器台数には 1 施設 2 台以上保有しているものも含まれる）

Table 9 Number of reimbursement request on treatment planning by its complexity and patient load/FTE radiation oncologist or number of new patients

管理料種類	放射線治療管理料数（放射線治療管理料総数に対する割合）			
	All facilities (n=495※1)	Heavy load/FTE R.O. institution in group B (n=29※1)	Heavy load/FTE R.O. institution in group A (n=56※1)	New patients≧800 institution in all facilities (n=15※1)
単純	65,398	4,900	13,810	8,103
（1 門照射，対向 2 門照射）	(53.3%)	(49.8%)	(49.9%)	(48.4%)
中間	32,095	2,710	7,639	4,843
（非対向 2 門照射，3 門照射）	(26.1%)	(27.6%)	(27.6%)	(28.9%)
複雑	25,317	2,225	6,220	3,810
（4 門以上の照射，運動照射，原体照射）	(20.6%)	(22.6%)	(22.5%)	(22.7%)
合計	122,810	9,835	27,669	16,756

※1 治療計画請求数が未記入であった施設を除いたデータから算出

Table 10　Special radiation therapy other than external irradiation according to patient load/FTE radiation oncologist or number of new patients

特殊照射	All facilities (n=712)	Heavy load/FTE R.O. institution in group B (n=48)	Heavy load / FTE R.O. institution in group A (n=72)	New patients≧800 institution in all facilities (n=19)
腔内照射				
施行施設数	181 (25.4%)	6 (12.5%)	42 (58.3%)	19 (100.0%)
治療症例数	3,246	43	959	569
組織内照射				
施行施設数	79 (11.1%)	1 (2.1%)	17 (23.6%)	14 (73.7%)
治療症例数	2,773	99	643	267
前立腺ヨード治療				
施行施設数	39 (5.5%)	1 (2.1%)	9 (12.5%)	6 (31.6%)
治療症例数	1,765	99	602	262
全身照射				
施行施設数	191 (26.8%)	16 (33.3%)	40 (55.6%)	16 (84.2%)
治療症例数	1,738	83	389	296
術中照射				
施行施設数	66 (9.3%)	2 (4.2%)	13 (18.1%)	8 (42.1%)
治療症例数	387	12	106	156
定位（脳）照射				
施行施設数	197 (27.7%)	21 (43.8%)	40 (55.6%)	16 (84.2%)
治療症例数	11,122	3,509	2,398	755
定位（体幹部）照射				
施行施設数	92 (12.9%)	8 (16.7%)	21 (29.2%)	13 (68.4%)
治療症例数	1,658	187	414	346
IMRT				
施行施設数	33 (4.6%)	2 (4.2%)	8 (11.1%)	10 (52.6%)
治療症例数	755	122	184	160
温熱併用照射				
施行施設数	36 (5.1%)	1 (2.1%)	6 (8.3%)	3 (15.8%)
治療症例数	581	10	82	39
Sr-90翼状片治療				
施行施設数	5 (0.7%)	0 (0.0%)	1 (1.4%)	0 (0.0%)
治療症例数	184	0	7	0

Table 11　Annual number of total cancer patients (new+repeat) treated for any of brain metastasis and bone metastasis by patient load/FTE radiation oncologist or number of new patients

転移	実患者数（放射線治療実患者総数に対する割合）			
	All facilities (n=712)	Heavy load/FTE R.O. institution in group B (n=48)	Heavy load/FTE R.O. institution in group A (n=72)	New patients≧800 institution in all facilities (n=19)
脳転移	15,321 (8.0%)	3,497 (18.1%)	2,758 (6.6%)	1,206 (5.2%)
骨転移	27,476 (14.4%)	2,219 (11.5%)	6,159 (14.8%)	2,931 (12.7%)

全体のがんに対する放射線治療適用率を現在の25%に留めている可能性がある[10]．一方，残り38%のA施設の上位25%の施設は，改善警告値[12]300人を超えた患者を治療しており，過剰労働状況にあった．現状のインフラのままでは患者数増加の吸収が困難となりつつある．この施設への放射線治療専門医の配置も優先的に進めなければならない．がん対策基本法，がんプロフェッショナル養成プランなどの追い風を得て，国全体で早急な人材育成を計るべきである．B施設の上位10%も改善警告値である年間300人を超えて治療しており，人員確保の標的となりうるが，内容を分

析してみると，そのうち半数の施設が定位(脳)照射に特化した施設であることが推定された．一方，診療放射線技師の場合は，放射線治療担当技師1名当たりの実患者数は117人であり，患者数に応じた配置がある程度できていると言える．しかし，この算定には治療計画や品質管理に関する業務を含めていないので，業務内容としては過剰と言える．品質管理士，医学物理士は，わが国の現状では多くが診療放射線技師と兼務である場合が多いので，それらの負荷を重複なく，今後算出しなければならない．今回はその部分のデータはない．日米ブルーブック[12), 13)]では，医学物理士は400～500人の患者に1人の配置が必要で，現状の負荷は1,000人を超えており，寡少である．

がん診療連携拠点病院は，全国平均よりも装備の機能は約10％ずつ充実しており，患者負荷も15～20％多かった．しかし，今回指定されたがん診療連携拠点病院の半数弱はB施設層であり，1 FTE以上の放射線治療担当医が確保されていなかった．がん診療連携拠点病院のB施設の平均患者数の負荷は約200名で，早急に常勤放射線治療担当医を確保すべきである．以上のように，放射線治療担当医は不足しているので，優先順位をつけながら，配置していくと同時に，当面は現状のスタッフ数で患者サービスを提供するために，地域の施設間の医療連携が特に重要である．これについて日本版ブルーブック[12)]に，施設規模および装置の機能別に具体的例を光森らにより提示している．よく言われているように，欧米のようながん患者の施設集中化をわが国で定着させるべきか否かは，医療従事者の待遇を含めた医療体制の根本に関わる現実的方策の中から考案しなければならない．現状からは放射線治療施設の地域分布についてわが国はよく実現できていると考える．一方，がんセンター・成人病センターや大学病院での患者数急増はこれらの施設の大型化，集中化が促されているのかもしれない．地域別の患者数負荷は各地域の患者数と担当のマンパワーに依存し，放射線治療担当医で3.2倍，放射線治療担当技師で2.6倍の地域差が観察された．特に負荷の多い地域では，人員の補充と周辺地域との連携が必要であろう．現在，基準値の範囲にある施設も今後の患者数の増加に備えるべく，人員補充を怠らないことが肝要である．本データが有効に利用されることを望む．

放射線治療担当医について，人員補充の標的と考えられるブルーブックの改善警告値を超える高負荷施設(300人/FTE放射線治療担当医以上)と大規模施設(新患800人以上)について全体データと比較して分析した．地域的にはB施設層は関東，信越・北陸により多く，同(A施設層)と大規模施設は関東，北海道により多かった．施設区分では高負荷施設(B施設層)はO，Hがより多く，同(A施設層)はGがより多く，大規模施設はほとんどUとGであった．これらの施設区分の病院を管轄する国・自治体において，患者数負荷増加の実態が理解され，人員補充が重点的に行われることを望む．ただ，同(B施設層)はTable 10，11から分かるように，半数にγナイフあるいは脳定位照射を行う施設が含まれていることが明らかであった．これらは分割回数が少ないため，一般外部照射の人員負荷の分析とは本来別にする必要がある．今回は厳密に区別できていない．装備は同(B施設層)でBrachytherapyが普及していないことを除いて，同(A施設層)，大規模施設になるにしたがって，全体の平均より充実していた．linac 1台あたりの年間患者数負荷は，いずれもブルーブックガイドライン[12)]の300人/装置を超えており，同(A施設層)と大規模施設では，さらに同改善警告値400人を凌駕していた．したがって，2005年時点でも，これらの施設91施設(72+19)にはlinac 1台の追加設置が必要と考えられた．治療計画の請求の種類は負荷が大きく，規模が大きいほど，単純が若干減少して，複雑がわずかに増加していた．大規模施設でも半数近くは単純であり，2005年でのわが国の診療実態を反映しており，患者数の負荷が，治療計画の複雑化，高精度化を阻害しているのかもしれない．特殊治療の施行数も，負荷が大きいほど増える傾向にあった．大規模施設では1 FTEあたりの患者数負荷はブルーブックのガイドラインの基準値200人/FTE放射線治療担当医の範囲にあるが，これらの施設区分はTable 7にあるように，40％はU：大学附属病院であり，教育，研究の責任が他の施設区分よりかなり高く，肝心の人材供給源であることも考慮すると，さらに多くの人員配置が必要であろう．

国全体で今後の患者数増加をどこで吸収するかという視点が重要となる．既述のように，欧米のような集中化，大型化は一つの方向性ではあるが，理想的過ぎるかもしれない．本調査で明らかとなったわが国の現状から，まずは，がん診療連携拠点病院での装備や人員の重点配備は現実的な選択肢であり，前進である．ただ，この指定とは関わりなく，地域の放射線治療に重要な貢献をしている施設は多数あることも明らかである．本調査では人員を早急に補充すべき施設をデータとしてある程度特定できた．いずれにしても人材育成と供給が最重要で，大学の果たす役割は大きい．並行して将来のスタッフとしての活躍の場を確保し，装備の整備も着実に進めていくことも課題である．各地域において本調査のデータが有効利用されることを希望する．地域の詳細な分析依頼にも常時応ずるものである．

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要旨：JASTROの2005年放射線治療施設構造調査を2006年３月から2007年２月までに調査票を送付して行った．回答率は96.9％(712/735)であった．1 FTE(full time equivalent)放射線治療担当医当たりが治療する年間実患者数(=患者負荷)は247人であった．施設層別化別の同様の値は≥1 FTE放射線治療担当医を有するA施設層で200人，<1 FTEのB施設層で159人であった(B施設層では過大評価を避けるため，本計算ではFTE=1として算出した．その施設の年間総患者数と同一)．A施設では全体の25％で，B施設の10％で300人以上(診療の質低下が懸念される改善警告値)を治療していた．放射線治療担当技師１名当たりの年間総患者数は117人であった．がん診療連携拠点病院では全国平均より優れた機能を装備したlinacならびにCT simulatorを使用していた．地域的に1 FTE放射線治療担当医当たりの年間患者総数は148～478人まで，また放射線治療担当技師１人当たりの年間患者数は73～191人までの顕著なバリエーションが観察された．1 FTE放射線治療担当医が年間300人以上(改善警告値)治療する高負荷施設(A施設層)と年間新規患者数が800人以上の大規模施設(計91施設)では，linac１台当たりの患者数が400人(改善警告値)を超過していた．

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CLINICAL INVESTIGATION

A MULTICENTER PHASE II STUDY OF LOCAL RADIATION THERAPY FOR STAGE IEA MUCOSA-ASSOCIATED LYMPHOID TISSUE LYMPHOMAS: A PRELIMINARY REPORT FROM THE JAPAN RADIATION ONCOLOGY GROUP (JAROG)

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Purpose: The aim of this study was to evaluate the efficacy and toxicity of moderate dose radiation therapy (RT) for mucosa-associated lymphoid tissue (MALT) lymphoma in a prospective multicenter phase II trial.
Methods and Materials: The subjects in this study were 37 patients with MALT lymphoma between April 2002 and November 2004. There were 16 male and 21 female patients, ranging in age from 24 to 82 years, with a median of 56 years. The primary tumor originated in the orbit in 24 patients, in the thyroid and salivary gland in 4 patients each, and 5 in the others. The median tumor dose was 30.6 Gy (range, 30.6–39.6 Gy), depending on the primary site and maximal tumor diameter. The median follow-up was 37.3 months.
Results: Complete remission (CR) or CR/unconfirmed was achieved in 34 patients (92%). The 3-year overall survival, progression-free survival, and local control probability were 100%, 91.9%, and 97.3%, respectively. Thirteen patients experienced Grade 1 acute toxicities including dermatitis, mucositis, and conjunctivitis. One patient developed Grade 2 taste loss. Regarding late toxicities, Grade 2 reactions including hypothyroidism, and radiation pneumonitis were observed in three patients, and Grade 3 cataract was seen in three patients.
Conclusions: This prospective phase II study demonstrated that moderate dose RT was highly effective in achieving local control with acceptable morbidity in 37 patients with MALT lymphoma. © 2007 Elsevier Inc.

MALT lymphoma, Radiation therapy, Local control, Acute toxicity, Late adverse event.

INTRODUCTION

Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue (MALT lymphoma) was first described in 1983 by Isaacson and Wright (1). After that, the revised European-American classification of lymphoid neoplasms (REAL) proposed it as a provisional entity (2), and the World Health Organization classification confirmed that it was a distinct disease entity (3). A recent nationwide study of malignant lymphoma among Japanese reported that it accounts for about 8.45% of all malignant lymphomas in Japan (4). Although it has been previously considered that only 5% to 10% of MALT lymphomas presented with Stage III or IV disease (5), several groups reported that 30% to 40% of MALT lymphomas were in advanced stages, and bone

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Conflict of interest: none.

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marrow involvement was found in 15% of patients (6–11). However, it has been well documented that MALT lymphomas demonstrate an indolent clinical course, regardless of the extent of the disease at presentation.

Because MALT lymphoma has been considered to be less responsive to standard chemotherapy than other aggressive lymphomas, radiation therapy (RT) or surgery has been used as the first line local treatment. Previous retrospective studies demonstrated excellent local control rates and progression-free survival (PFS) after RT (12–27). However, RT for orbital MALT lymphomas usually leads to late adverse events such as retinopathy, cataracts, or dry eye (12–21). In addition, with regard to the RT technique, the total dose and irradiated volume varies in the literature, with some reports containing other low-grade B-cell lymphomas such as small lymphocytic lymphoma or follicular lymphoma, which hampered investigators from establishing optimal radiotherapeutic parameters (12–15, 17–21). Furthermore, there have been no published prospective trials evaluating the appropriate dose and field of RT for MALT lymphoma, except for patients with localized gastric disease (26). Thus we conducted a multicenter phase II study to evaluate moderate dose (30.6–39.6 Gy) of RT, depending upon the primary site and tumor bulk. We present here our preliminary report with regard to the efficacy and toxicity of this regimen for localized MALT lymphoma.

METHODS AND MATERIALS

Eligibility criteria

Eligible patients had previously untreated, histologically proven MALT lymphoma with Stage IEA according to the Ann Arbor staging system. Patients with simultaneous or metachronous bilateral disease in the orbit, salivary gland, or breast were also eligible; however, those who demonstrated stomach or spleen involvement were excluded from this study. Patients had to be >19 years of age, with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. The trial was conducted in accordance with the Declaration of Helsinki, with approval of the institutional review board at each institution. All patients provided written informed consent.

Staging and treatment

For staging of their disease, patients underwent a history and physical examination, complete blood counts, screening blood tests of hepatic and renal function, gallium scintigraphy, computed tomography (CT) of the head and neck, chest, abdomen and pelvis, esophagogastroduodenoscopy, and a bone marrow biopsy. All patients, who were treated by photons, received RT from a linear accelerator with an appropriate energy in accordance with the primary site. An appropriate energy electron field was applied to treat patients with conjunctival disease. The total dose of RT was dependent on the tumor location and its maximum diameter. Patients with orbital disease or those who had minimal residual disease after surgical removal received 30.6 Gy in 17 fractions. Tumors <6 cm received RT with 36 Gy in 20 fractions, and those with ≥6 cm of disease were treated 39.6 Gy in 22 fractions. The clinical target volume (CTV) was defined as an entire involved organ (orbit, thyroid, salivary gland, breast) or gross tumor volume (GTV) with at least 20 mm of margin. We did not intend to treat the adjacent first echelon lymph node region. A lens shield was placed unless the block compromised tumor coverage. Radiation doses were specified according to the report of ICRU 50.

Central pathology review and radiotherapy quality assurance

After the enrollment of the patients, unstained formalin-fixed paraffin sections of the diagnostic biopsy specimen were collected and sent to the central review board office. Hematoxylin-eosin-stained sections were histologically reviewed according to the World Health Organization classification by the central pathology review board for this study. For this purpose, immunohistochemical study using antibodies against CD3 (PS1, Novocastra, Newcastle upon Tyne, UK), CD5 (4C7, Novocastra, Newcastle upon Tyne, UK), CD10 (56C6, Novocastra), CD20 (L26, DakoCytomation, Glostrup, Denmark), BCL-2 (clone 124, DakoCytomation), and cyclin D1 (rabbit polyclonal antibody, MBL, Nagoya, Japan) were also performed. The diagnosis of the central pathology review board was regarded as the final one in cases where there was discrepancy between the diagnoses made by an institution and the board. All radiologic films or color photos that depicted extent of disease, radiation simulation films, port films, and RT charts were reviewed, and compliance with the protocol was judged in terms of field border placement, dose fractionation, and dose constraint to risk organs by the members of quality assurance (QA) subcommittee. The central pathologic review and radiotherapy QA were undertaken after planned registration was over. Neither pathologic review nor RT treatment plan review was performed before actual treatment.

Statistical methods

Primary end point of this study was progression-free survival (PFS). Previous retrospective series have shown that PFS was approximately 70% at 3 years after treatment (6). It was estimated that 35 eligible patients would have an 80% power of detecting an improvement in the expected 3-year PFS for this trial of 15% with a significance level of 0.05. To allow for exclusion after central histopathologic review, 40 patients were recruited for this study. The PFS was defined as the date from protocol registration to the date of reappearance of disease, progression of existing disease, or death from this MALT lymphoma, whichever was first. Other end points were overall survival (OS), local control probability (LC), response rate, and acute and late toxicities regarding RT. The OS, PFS, and LC were calculated using the method of Kaplan and Meier (28). Response was assessed using standard criteria (29). Acute toxicity was graded according to the National Cancer Institute Common Toxicity Criteria (version 2.0). Late effects were graded according to the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer late radiation morbidity scoring scheme.

RESULTS

Patient characteristics

From April 2002 to November 2004, 40 patients were recruited from 12 institutions in Japan. Three patients were deemed ineligible after central pathologic review (low-grade B-cell non-Hodgkin's lymphoma, further unspecified in 2 patients, reactive lesion could not be excluded in 1 patient). Thus the remaining 37 patients were included in the present analysis. Detailed patient characteristics are shown in Table 1. There were 16 male and 21 female patients, ranging in age from 24 to 82 years, with a median of 56 years. The

Table 1. Patient characteristics

Characteristics	No. of patients (%)
Age (years)	
Range	24–82
Mean ± SD	55 ± 14
Median	56
Sex	
Male	16 (43)
Female	21 (57)
Primary site	
Orbit	24 (65)
Conjunctival cases	17/24
Thyroid	4 (11)
Salivary gland	4 (11)
Waldeyer's ring	2 (5)
Prostate	1 (3)
Lung	1 (3)
Cecum	1 (3)

Abbreviation: SD = standard deviation.

primary tumor originated in the orbit including the conjunctiva in 24 patients, the thyroid in 4 patients, salivary gland in 4, Waldeyer's ring in 2, and prostate, lung, and cecum in 1 patient each. Two patients demonstrated bilateral conjunctival tumors at presentation. Two patients showed lactate dehydrogenase elevation. No patients had B symptoms because of the exclusion criteria in this study. Follow-up ranged from 19.6 to 52.9 months, with a median of 37.3 months.

Compliance, response, and survival

With regard to quality assurance of RT, 34 of 37 patients (92%) were judged per protocol, and the remaining 3 were acceptable deviations. Of the 3 acceptable deviations, 2 had insufficient margin placement around the CTV, and the remaining patient received protracted RT for personal reasons. Figure 1 provides an example of a digitally reconstructed radiograph (DRR) showing irradiation field and portal film for a patient with orbital MALT lymphoma. The median dose of RT was 30.6 Gy, and 27 patients received 30.6 Gy. Seven patients received 36 Gy, and the remaining 3 patients received 39.6 Gy. Four patients with conjunctival tumor received RT with lens shield. At the time of evaluation, 33 patients achieved complete remission (CR) or CR/unconfirmed (CRu), which resulted in an 89.2% CR rate (95% confidence interval [CI], 78.7–99.7%). The remaining four patients obtained partial remission (PR). Three patients experienced recurrence during the study period. Two recurrences occurred outside of the irradiation field, and the remaining one with a conjunctival tumor experienced local recurrence behind the lens block. Three-year PFS and LC were 91.9% (95% CI, 83.1–100%) and 97.3% (95% CI, 92.1–100%), respectively. As no patients died of any causes during the study period, 3-year OS was 100%. The disease control outcomes are summarized in Table 2.

Acute toxicities and late sequelae

A summary of the acute and late toxicities are shown in Table 3. Eighteen Grade 1 acute toxicities including dermatitis, mucositis, and conjunctivitis developed in 13 patients. One patient developed Grade 2 taste loss. With regard to late toxicities, Grade 1 reactions including pigmentation, hypothyroidism, and dry mouth were observed in 1 patient each. Three patients developed Grade 2 reactions including hypothyroidism, radiation pneumonitis. Three patients received surgery for cataract (Grade 3 reaction).

DISCUSSION

This is the first prospective study to evaluate the efficacy and toxicity of moderate dose RT for MALT lymphoma not originating in the stomach. We have demonstrated that the LC and PFS were 97.3%, and 91.9% at 3 years, respectively. Our findings demonstrated that RT was highly effective in achieving local control for localized MALT lymphoma. These favorable outcomes after RT are consistent with previous retrospective studies, which administered various doses of RT with a median of 25 to 40.5 Gy (12–21, 23–27). However, most of these studies delivered >40 Gy to some patients, and the fact that they included low-grade B-cell lymphomas other than MALT lymphomas obscured our understanding of the optimal dose of RT in the management of this lymphoma. Despite these limitations, many researchers concluded that 30 Gy of RT could achieve excellent local control. In our retrospective analysis for ocular adnexal MALT lymphoma, we did not find that higher than 30 Gy of RT produced any additional benefits compared with doses ≤30 Gy (30). These and our current findings strongly suggest that 30.6 Gy is appropriate for controlling ocular MALT lymphoma, and MALT lymphoma at other sites with minimal residual disease after surgery.

Although several groups treating solely MALT lymphoma mentioned that 25 to 30 Gy is enough to control the disease (23, 25), we could not determine whether lower doses would improve the therapeutic ratio, as no patients in this study received doses <30 Gy.

The next problem that should be resolved is the optimal target volume for MALT lymphoma. There are only a few studies that clearly demonstrate the target volume in the literature (14, 19–21, 23, 25–27). Moreover, as previously mentioned, these studies include low grade non-Hodgkin's lymphoma other than MALT lymphoma. For gastric MALT lymphomas, the entire stomach and perigastric nodes are considered to be the target volume (26, 27). Olivier *et al.* (20) also delivered RT to the affected parotid gland with or without the first-echelon node for parotid lymphoma. However, recurrences of MALT lymphoma usually occur at other mucosal sites, and the significance of RT to the echelon lymph nodes is unknown. On the one hand, Pfeffer *et al.* (31) showed that 4 of 12 patients with orbital lymphoma who received partial orbital irradiation experienced recurrence. In addition, we observed that 1 of 4 patients with conjunctival MALT lymphoma receiving RT with a lens shield developed local recurrence at 15 months after RT in this study. Thus it seems reasonable that the target volume for MALT lymphoma should include the entire affected organ.

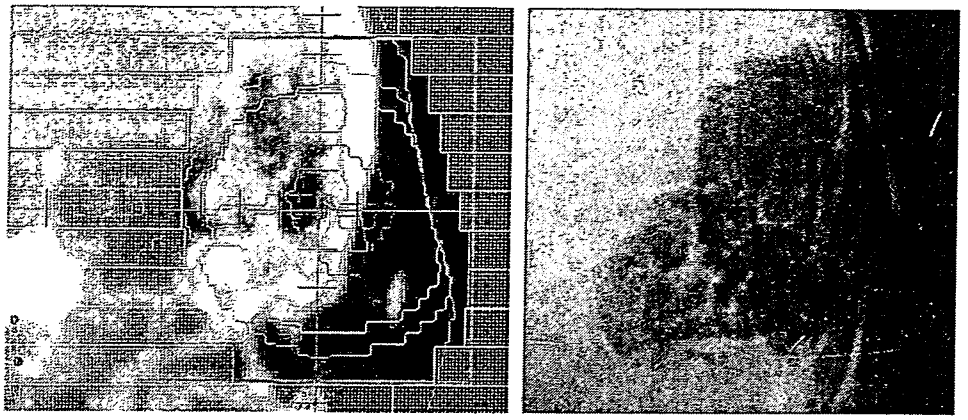

Fig. 1. Digitally reconstructed radiograph showing irradiation field (left) and portal film (right) for patient with orbital mucosa-associated lymphoid tissue (MALT) lymphoma.

It is well recognized that local RT is effective in controlling MALT lymphoma, on the one hand, and a pathologic link between some infectious agents, mainly bacteria and viruses, and MALT lymphoma has also been clearly established. It is also well known that gastric MALT lymphoma is closely associated with chronic gastritis caused by *Helicobacter pylori* (*H. pylori*) infection, and its eradiation achieved tumor regression in 70% to 80% of patients (32–34). Thus, it has been widely accepted that *H. pylori* eradiation is the first line treatment for *H. pylori*–positive gastric MALT lymphoma. Furthermore, small pilot studies demonstrated that high-grade MALT lymphoma or diffuse large B-cell lymphoma with areas of MALT lymphoma originating in the stomach also regressed after *H. pylori* eradication (35, 36). Recently, Ferreri *et al.* (37) demonstrated that *Chlamydia psittaci* (*C. psittaci*) DNA has been detected in 80% of ocular adnexal MALT lymphoma. They treated 9 patients with *C. psittaci* DNA-positive MALT lymphoma with antibiotic therapy, and found that 7 patients responded to the treatment with two CRs (38). Moreover, some cases of tumor regression after antimicrobial therapy have been reported in *Borrelia burgdorferi* associated cutaneous MALT lymphomas (39, 40). However, in the most extensively evaluated gastric MALT lymphomas associated with bacterial infection, several groups have reported that pathologic CR after *H. pylori* eradication did not guarantee molecular CR (41). Thus, whether antibiotic therapy could replace RT, surgery or chemotherapy as the first line treatment against localized MALT lymphoma should be evaluated in large, confirmatory clinical trials. Furthermore, three groups (42–44) have recently observed considerably lower prevalence of *C. psittaci* infection in patients with ocular adnexal lymphoma than that reported by Ferreri *et al.* (37).

Table 2. Summary of the treatment outcomes

Outcome	
Complete remission / Complete remission unconfirmed	33/37 (89.2%)
Partial remission	4/37 (10.8%)
Local control at 3 years	97.3%
Progression-free survival at 3 years	91.9%
Overall survival at 3 years	100%

Chemotherapy has also become another therapeutic option for MALT lymphoma. Several phase II studies demonstrated antitumor activity of the purine analogs fludarabine and cladribine (45, 46). Other groups have also shown that the anti-CD20 monoclonal antibody rituximab was effective for MALT lymphoma (47, 48). These findings also will be further elucidated in large scale clinical trials.

It usually takes a long time to develop late adverse events and recurrence after local RT. Late adverse events after local RT are described in the literature when treating orbital lymphoma. These included cataracts, dry eye, keratitis, and retinopathy (12–21, 25). Several groups reported that more than 34 or 35 Gy of RT increased the risk of late adverse events (15, 19). It should be emphasized that 30.6 Gy of RT caused Grade 3 cataract in three patients with a median follow-up of only 37.3 months. Some groups have reported that a lens shield can reduce late adverse events, especially cataract formation, without jeopardizing the local control rate (13, 14, 21, 25), but others did not (15–18). We recommend that physicians use caution when they apply a lens shield for conjunctival MALT lymphoma, because 1 of 4 patients with conjunctival tumor who were treated with a lens block in place experienced recurrence behind it.

Table 3. Summary of the acute and late toxicities

	No. of patients (%)			
	Grade 0	Grade 1	Grade 2	Grade 3
Acute toxicities				
Skin reaction	31 (84%)	6 (16%)	0	0
Conjunctivitis	31 (84%)	6 (16%)	0	0
Mucositis	31 (84%)	6 (16%)	0	0
Taste loss	36 (97%)	0	1 (3%)	0
Late toxicities				
Skin reaction	36 (97%)	1 (3%)	0	0
Dry mouth	36 (97%)	1 (3%)	0	0
Hypothyroidism	34 (92%)	1 (3%)	2 (5%)	0
Pneumonitis	36 (97%)	0	1 (3%)	0
Cataract	34 (92%)	0	0	3 (8%)

Although we observed three (8%) recurrences with a median follow up of 37.3 months, Wenzel *et al.* (22) reported that 43% of patients experienced recurrence after local treatment with a median of 11 months. Furthermore, Raderer *et al.* (49) recommended lifelong observation of all patients treated for MALT lymphoma because they documented late relapses with a median of 47 months. We have to extend follow-up prospectively to evaluate not only recurrence, but also the frequency and severity of late adverse events.

In conclusion, the preliminary results from this prospective phase II study confirm that RT was highly effective in achieving local control for localized MALT lymphoma, and 30.6 Gy was appropriate for controlling orbital MALT lymphoma and MALT lymphoma at other sites with minimal residual disease after extirpation without severe detrimental effects, which is consistent with many previous retrospective studies. However, we would acknowledge that our findings are best generalized to orbital MALT lymphoma, since two-thirds of the enrolled patients had disease at an orbital site. Furthermore, as we observed three Grade 3 cataract during this study period, we should emphasize that longer follow-up is indispensable to elucidate long-term local control probability and additional late effects from RT.

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REVIEW

Radical external beam radiotherapy for prostate cancer in Japan: differences in the patterns of care among Japan, Germany, and the United States

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Abstract Optimal management of radiotherapy for prostate cancer patients has become a major concern for physicians in Japan. We reviewed published reports identifying the differences in the patterns of care for prostate cancer patients treated with radical external beam radiotherapy in Japan, Germany, and the United States. The reports indicate that Japanese patients have more advanced primary disease than patients in Germany or the United States. These patient characteristics for Japan and the United States have been almost unchanged for several years. Regarding radiotherapy, conformal radiotherapy was less frequently administered to patients in Japan than patients in Germany or the United States, and the total radiation dose was higher in Germany and the United States than in Japan. Concerning changes in trends in the patterns of radiotherapy, the percentage of patients treated with higher dose levels in the United States has rapidly increased, whereas the percentage of patients receiving these dose levels in Japan has remained extremely low. On the other hand, hormonal therapy has been used more frequently in Japan than in Germany or the United States. These findings indicate that patient characteristics and patterns of care for prostate cancer in Japan are considerably different from those in Germany or the United States.

Key words Patterns of Care Study · Prostate cancer · Type of institution · Radiation therapy · Hormone therapy

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Introduction

In Japan, the number of deaths due to prostate cancer has been steeply increasing, especially among elderly patients. The proportion of prostate cancer deaths among total cancer deaths also increased from 0.9% in 1960 to 4.2% in 2000.[1] Since entering the prostate-specific antigen (PSA) era, clinicians are detecting disease at an earlier stage, and the rates of successful treatment for early-stage patients are at historical highs. Moreover, radiotherapy has become much more common because of significant advances in treatment planning technology and methodology. Therefore, the optimal management of radiotherapy for prostate cancer patients has become a major concern in Japan. However, we have not been able to evaluate national practice processes properly owing to the limited information available.

The Patterns of Care Study (PCS) national survey is a retrospective study designed to establish national practice processes for selected malignancies over a specific time period.[2–4] In addition to documenting the practice process, the PCS is important for developing and disseminating national guidelines for cancer treatment that help promote a high-quality process of care in the country. To improve the quality of radiation oncology, PCS methodology was introduced to Japan from the United States.[5,6] The Japanese PCS Working Group of Prostate Cancer started a nationwide survey for patients who underwent radiotherapy between 1996 and 1998.[7,8] Subsequently, a second PCS of Japanese patients treated between 1999 and 2001 was conducted, and we have previously reported the results of the first and the second PCS regarding radical external beam radiotherapy for prostate cancer patients.[9–13]

In the current study, we reviewed the published reports of the Japanese 1999–2001 PCS study,[11] the German 1998–2000 PCS study,[14] and the 1999 United States PCS study,[15] focusing on differences in the patterns of care between Japan, Germany, and the United States during approximately the same time periods. In addition, we reviewed the changes in trends in the patterns of radiotherapy for prostate cancer patients in Japan and the United States by comparing their most recent PCS results.[10] Although the PCS results of Germany were derived from only a few institutions, we believe these results should at least roughly represent the German national averages in the patterns of care for prostate cancer.

Comparison of patient characteristics among Japan, Germany, and the United States

Ogawa et al. previously indicated that during the period of 1999–2001, most prostate cancer patients in Japan treated with radical external beam radiotherapy had advanced disease, with more than 80% of patients having intermediate or unfavorable risk diseases[11] (Table 1). In contrast, Zelefsky et al. showed that in the United States many prostate cancer patients had early-stage disease during 1999.[15] A comparison of patients in Japan with those in the United States found that the Japanese patients had more advanced disease than their U.S. counterparts.[12] The current study compared patients in Japan with those in Germany, as reported by Vordermark et al.,[14] and found that Japanese patients once again had more advanced disease than their German counterparts. Compared with their German and U.S. counterparts, Japanese patients had higher pretreatment PSA levels, more advanced T stage, and a higher proportion of Gleason scores of 8–10. The median PSA level in Japan was 20.0 ng/ml versus 11.3 ng/ml in Germany and <10 ng/ml in the United States. The median Gleason combined score and the percentage of Gleason combined scores of 8–10 were 7 and 34.5% in Japan, respectively, whereas the median Gleason combined score was 6 in Germany and the percentage of Gleason combined score of 8–10 was 18.8% in the Unites States. The percentage of T3-4 tumors was 45.6% in Japan versus 32.0% and 6.8% in Germany and in the United States, respectively. Moreover, comparing risk groups between Japan and the United States, the proportion of Japanese patients in the unfavorable risk group was 50.4% versus 24.0% in the United States. These results indicate that higher proportions of patients with advanced disease were treated with radical external beam radiotherapy in Japan than in Germany or the United States. Whether these differences among patients in Japan, Germany, and the United States resulted from differences in access to medical care or from biological differences between the tumors themselves remains unknown. Further investigation of potential differences in disease characteristics between individuals in these countries would be informative.

Changing trend in patient characteristics for Japan and the United States

Ogawa et al. compared the changes in patient characteristics for Japan and the United States, comparing their most recent PCS (1999–2001 Japan PCS and 1999 U.S. PCS) with their previous PCS (1996–1998 Japan PCS and 1994 U.S. PCS). They found that the patient characteristics in for both countries had remained almost unchanged between the study periods[12] (Table 2). Although the incidence of the patients with T3-4 diseases significantly decreased at 1999–2001, Japanese patients treated with radical radiotherapy continued to exhibit advanced disease (PSA >20 ng/ml and Gleason combined scores of 8–10). On the other hand, the proportion of U.S. patients with advanced disease remained low from 1994 to 1999. These results thus demonstrate persistence of the trend for Japanese patients to have more advanced

Table 1. Patient and treatment characteristics: comparison of PCS results among Japan, Germany, and the United States

Parameter	Japan/1999–2001[a]	Germany/1998–2000[b]	United States/1999[c]
No. of institutions	76	6	58
No. of patients investigated	283	148	392
Patient characteristics			
Age (years)			
Median	72	—	71
Mean	71.8	69	70.8
Pretreatment PSA level (ng/ml)			
Median	20.0	11.3	<10[d]
Mean	90.0	32.1	—
<10	28.7%	—	60.5%
≥10 but <20	21.3%	—	23.0%
≥20	50.0%	—	15.5%
Unknown	—	—	1.0%
Gleason combined score			
Median	7	9	≤6[e]
Mean	6.5	5.8	—
2–6	45.0%	—	54.3%
7	20.5%	—	25.8%
8–10	34.5%	—	18.8%
Unknown	—	—	1.1%
T stage			
TX-T0	0%	0%	7.8%
T1	8.1%	33.0%	43.9%
T2	40.1%	26.0%	33.7%
T3–4	45.6%	32.0%	6.8%
Unknown	2.6%	9.0%	7.8%
N stage			
N0	83.10%	87.0%	—
N1	6.40%	13.0%	—
Nx	9.40%	—	—
Risk group (%)			
Favorable	14.5%[g]	—	38.3%[f]
Intermediate	35.1%[g]	—	37.7%[f]
Unfavorable	50.4%[g]	—	24.0%[f]
Radiotherapy			
Energy (> 10 MV) (%)			
Yes	74.3%	—	73.0%
CT-based treatment planning			
Yes	85.5%	—	95.0%
Conformal therapy			
Yes	43.0%	100%	80.0%
Radiation dose (Gy)			
Median	68.4	—	—
Mean	66.0	69.1	—
Higher dose levels (≥ 72 Gy)			
Yes	7.5%	—	43.0%
Administration of pelvic irradiation			
Yes	33.0%	28.5%	23.2%
Hormonal therapy			
Yes	89.7%	70.5%	51.3%

PCS, patterns of care study; PSA, prostate-specific antigen; CT, computed tomography

[a] Ogawa et al.[11]

[b] Vordermark et al.[14]

[c] Zelefsky et al.[15]

[d] Because 60.5% of patients had PSA values <10 ng/ml, the median should be <10 ng/ml

[e] Because 54.3% of patients had Gleason combined score of 2–6, the median should be ≤6

[f] Favorable, zero adverse features; intermediate, one adverse features; unfavorable, two or more adverse features. Adverse features: PSA >10 ng/ml; Gleason combined score >6; T stage ≥3

[g] Favorable, zero adverse features; intermediate, one adverse features; unfavorable, two or more adverse features. Adverse features: PSA >10 ng/ml; poor differentiation; T stage ≥3