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，linac 1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

JAPANESE STRUCTURE SURVEY OF RADIATION ONCOLOGY IN 2005 BASED ON INSTITUTIONAL STRATIFICATION OF PATTERNS OF CARE STUDY

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Purpose: To evaluate the structure of radiation oncology in Japan in terms of equipment, personnel, patient load, and geographic distribution to identify and improve any deficiencies.

Methods and Materials: A questionnaire-based national structure survey was conducted between March 2006 and February 2007 by the Japanese Society of Therapeutic Radiology and Oncology. These data were analyzed in terms of the institutional stratification of the Patterns of Care Study.

Results: The total numbers of new cancer patients and total cancer patients (new and repeat) treated with radiotherapy in 2005 were estimated at approximately 162,000 and 198,000, respectively. In actual use were 765 linear accelerators, 11 telecobalt machines, 48 GammaKnife machines, 64 ^{60}Co remote-controlled after-loading systems, and 119 ^{192}Ir remote-controlled after-loading systems. The linear accelerator systems used dual-energy function in 498 systems (65%), three-dimensional conformal radiotherapy in 462 (60%), and intensity-modulated radiotherapy in 170 (22%). There were 426 Japanese Society of Therapeutic Radiology and Oncology-certified radiation oncologists, 774 full-time equivalent radiation oncologists, 117 medical physicists, and 1,635 radiation therapists. Geographically, a significant variation was found in the use of radiotherapy, from 0.9 to 2.1 patients/1,000 population. The annual patient load/FTE radiation oncologist was 247, exceeding the Blue Book guidelines level. Patterns of Care Study stratification can clearly discriminate the maturity of structures according to their academic nature and caseload.

Conclusion: The Japanese structure has clearly improved during the past 15 years in terms of equipment and its use, although the shortage of manpower and variations in maturity disclosed by this Patterns of Care Study stratification remain problematic. These constitute the targets for nationwide improvement in quality assurance and quality control. © 2008 Elsevier Inc.

Structure survey, Radiotherapy facility, Radiotherapy personnel, Radiotherapy equipment, Caseload.

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INTRODUCTION

The medical care systems of the United States and Japan have very different backgrounds. In 1990, the Patterns of Care Study (PCS) conducted a survey of the 1989 structure of radiation oncology facilities for the entire census of facilities in the United States. The results of the survey, together with trends in the structure of specialization since 1974, were reported in detail by Owen *et al.* (1). In 1991, the Japanese Society of Therapeutic Radiation Oncology (JASTRO) conducted the first national survey of the structure of radiotherapy (RT) facilities in Japan based on their status in 1990, with the results reported by Tsunemoto (2). The first comparison of these two national structure surveys to illustrate the similarities and differences present in 1989–1990 was conducted by Teshima *et al.* (3) and reported in 1995. The resultant international exchange of information proved valuable for both countries, because each could improve their own structure of radiation oncology using those data.

The Japanese structure of radiation oncology has improved in terms of the greater number of cancer patients who are treated with RT, as well as the public awareness of the importance of RT, although problems still exist that should be solved. The JASTRO has conducted national structure surveys every 2 years since 1990 (4). In Japan, an anticancer law was enacted in 2006 in response to patients' urgent petitions to the government. This law strongly advocates the promotion of RT and increasing the number of radiation oncologists (ROs) and medical physicists. The findings of the international comparisons and the consecutive structural data gathered and published by the JASTRO have been useful in convincing the Japanese bureaucracy of the importance of RT. In this report, the recent structure of radiation oncology in Japan is presented, with reference to data obtained from previous international comparisons.

METHODS AND MATERIALS

Between March 2006 and February 2007, the JASTRO conducted a questionnaire using a national structure survey of radiation oncology in 2005. The questionnaire included the number of treatment machines by type, number of personnel by category, and number of patients by type, site, and treatment modality. For variables measured over a period, data were requested for the calendar year 2005. The response rate was 712 (96.9%) of 735 of active facilities. The data from 511 institutions (69.5%) were registered in the International Directory of Radiotherapy Centres in Vienna, Austria in April 2007.

The PCS was introduced in Japan in 1996 (5–11). The PCS in the United States used structural stratification to analyze the national averages for the data in each survey item using two-stage cluster sampling. The Japanese PCS used similar methods. We stratified the RT facilities nationwide into four categories for the regular structure surveys. This stratification was based on academic conditions and the annual number of patients treated with RT in each institution, because the academic institutions require, and have access to, more resources for education and training and the annual caseload also constitutes essential information related to structure. For the present study, the following institutional stratification was used: A1, university hospitals/cancer centers treating ≥440 patients/y; A2, the same type of institutions treating ≤439 patients/y; B1, other national/public hospitals treating ≥130 patients/y; and B2, other national hospital/public hospitals treating ≤129 patients/y.

The Statistical Analysis Systems, version 8.02 (SAS Institute, Cary, NC), software program (12) was used for statistical analyses, and statistical significance was tested using the chi-square test, Student *t* test, or analysis of variance.

RESULTS

Current situation of radiation oncology in Japan

Table 1 shows that the numbers of new patients and total patients (new plus repeat) requiring RT in 2005 were estimated at approximately 162,000 and 198,000, respectively. According to the PCS stratification of institutions, almost 40% of the patients were treated at academic institutions (categories A1 and A2), even though these academic institutions constituted only 18% of the 732 RT facilities nationwide.

The cancer incidence in Japan in 2005 was estimated at 660,578 (13) with approximately 25% of all newly diagnosed patients treated with RT. The number has increased steadily during the past 10 years and is predicted to increase further (4).

Facility and equipment patterns

Table 2 lists the RT equipment and related function. In actual use were 767 linear accelerators, 11 telecobalt machines, 48 Gamma Knife machines, 65 ^{60}Co remote-controlled afterloading systems (RALSs), and 119 ^{192}Ir RALSs. The linear accelerator system used dual-energy function in 498 systems

Table 1. PCS stratification of radiotherapy facilities in Japan

Institution Category	Description	Facilities (*n*)	New patients (*n*)	Average new patients/facility* (*n*)	Total patients (new + repeat) (*n*)	Average total patients/facility* (*n*)
A1	UH and CC (≥440 patients/y)	66	45,866	694.9	54,885	831.6
A2	UH and CC (<440 patients/y)	67	17,161	256.1	21,415	319.6
B1	Other (≥130 patients/y)	290	71,627	247.0	88,757	306.1
B2	Other (<130 patients/y)	289	21,664	75.0	26,116	90.4
Total		712	156,318†	219.5	191,173†	268.5

Abbreviations: PCS = Patterns of Care Study; UH = university hospital; CC = cancer center hospital; Other = other national, city, or public hospital.

* $p < 0.0001$.

† Number of radiotherapy institutions was 735 in 2005, and number of new patients was estimated at approximately 162,000; corresponding number of total patients (new plus repeat) was 198, 000.

Table 2. Equipment, its function and patient load per equipment by PCS institutional stratification

RT equipment and function	A1 (n = 66) n	%	A2 (n = 67) n	%	B1 (n = 290) n	%	B2 (n = 289) n	%	p	Total (n = 712) n	%
Linear accelerator	133		85		283		264		—	765	
With dual energy function	97	72.9*	62	72.9*	197	69.6*	142	53.8*	<0.0001	498	65.1*
With 3D-CRT function (MLC width ≤1.0 cm)	109	82.0*	59	69.4*	176	62.2*	118	44.7*	<0.0001	462	60.4*
With IMRT function	65	48.9*	25	29.4*	55	19.4*	25	9.5*	<0.0001	170	22.2*
Annual patients/linear accelerator	412.7†		243.8†		279.9†		93.4†		<0.0001	234.6†	
Particle	5		0		1		1		—	7	
Tomotherapy	0		0		0		1		—	1	
Microtron	8		3		9		4		—	24	
Telecobalt (actual use)	7 (5)		6 (1)		7 (1)		14 (4)		—	34 (11)	
Gamma Knife	6		3		32		7		0.0004	48	
^{60}Co RALS (actual use)	8 (8)	12.1‡ (12.1)	13 (12)	19.4‡ (17.9)	41 (36)	14.1‡ (12.4)	12 (8)	4.2‡ (2.8)	<0.0001	74 (64)	10.4‡ (9.0)
^{192}Ir RALS (actual use)	53 (52)	80.3‡ (78.8)	27 (24)	38.8‡ (34.3)	35 (35)	12.1‡ (12.1)	8 (8)	2.8‡ (2.8)	<0.0001	123 (119)	17.1‡ (16.6)
^{137}Cs RALS (actual use)	0 (0)		0 (0)		2 (2)		0 (0)		—	2 (2)	

Abbreviations: PCS = Patterns of Care Study; RT = radiotherapy; 3D-CRT = three-dimensional conformal radiotherapy; MLC = multileaf collimator; IMRT = intensity-modulated radiotherapy; RALS = remote-controlled after-loading system.

* Percentage calculated from number of systems using this function and total number of linear accelerator systems.

† Percentage calculated from number patients and number of institutions with linear accelerators; institutions without linear accelerators excluded from calculation.

‡ Percentage of institutions that have this equipment (≥2 pieces of equipment per institution).

(65%), three-dimensional conformal RT in 462 (60%), and intensity-modulated RT (IMRT) in 170 (22%). These functions were installed more frequently in the equipment of academic institutions than in that of nonacademic institutions (p < 0.0001). The annual numbers of patients/linear accelerator were 413 for A1, 244 for A2, 280 for B1, and 93 for B2 institutions. The number of institutions with telecobalt machines in actual use showed a major decrease to 11. The Gamma-Knife machine was installed more frequently in B1 institutions. A significant replacement of ^{60}Co RALS by ^{192}Ir RALS was observed, especially in academic institutions. We had seven particle machines, three with carbon beam and five with proton beam RT. The total number of patients treated at the seven institutions was estimated at approximately 1,600 (1% of all new patients in Japan). Eleven advanced institutions were included in the A1 category and treated >800 patients annually. They were equipped with linear accelerators with dual-energy function (71% of the institutions), three-dimensional conformal RT function (89%) and IMRT function (70%), as well as with ^{192}Ir-RALS (90%) and a computed tomography (CT) simulator (100%).

Table 3 lists the RT planning and other equipment. X-ray simulators were installed in 70% of all institutions, and CT simulators in 55%. A significant difference was found in the rate of CT simulator installation by institutional stratification, from 91% in A1 to 45% in B2 institutions (p < 0.0001). Only a very few institutions used magnetic resonance imaging for RT, although computer use for RT recording was pervasive.

Staffing patterns and patient loads

Table 4 lists the staffing patterns and patients loads by institutional stratification. The total number of full-time equivalent (FTE) ROs in Japan was 774. The average number of FTE ROs was 4.41 for A1, 1.43 for A2, 0.89 for B1, and 0.45 for B2 institutions (p < 0.0001). The patient load/FTE RO in Japan was 247, and the number for A1, A2, B1, and B2 institutions was 189, 224, 343, and 202, respectively (p < 0.0001), with the patient load for B1 institutions by far the greatest. In Japan, 40% of the institutions providing RT had their own designated beds, and ROs must also take care of their inpatients. The percentage of distribution of institutions by patient load/FTE RO is shown in Fig. 1 and indicates that the largest number of facilities featured a patient/FTE staff level of 101–150, with 151–200 the second largest number. More than 60% of the institutions (438 of 712) had <1 FTE RO, as shown by the gray areas of the bars.

A similar trend for radiation technologists and their patient load by stratification of institutions was observed (p < 0.0001). The percentage of distribution of institutions by patient load/radiation technologist is also shown in Fig. 2. The largest number of facilities had a patient/RT technologist level in the 81–100 range, with 101–120 the second largest number. There were 117 full-time (and 30 part-time) medical physicists and 257 full-time (and 13 part-time) RT quality assurance staff. In this survey, duplication reporting of these personnel numbers could not be checked because of a lack of

Table 3. Radiotherapy planning and other equipments by PCS institutional stratification

RT planning and other equipment	A1 ($n = 66$)		A2 ($n = 67$)		B1 ($n = 290$)		B2 ($n = 289$)			Total ($n = 712$)	
	n	%	n	%	n	%	n	%	p	n	%
X-ray stimulator	58	84.8*	53	76.1*	201	68.6*	190	65.7*	0.0130	502	69.7*
CT stimulator	66	90.9*	48	68.7*	163	54.8*	130	44.6*	<0.0001	407	55.3*
RTP computer (≥2)	209 (190)	100* (71.2)	114 (82)	94.0* (46.3)	336 (101)	95.9 (14.8)	281 (50)	88.6* (8.7)	0.0005 (<0.0001)	940 (146)	93.1* (20.5)
MRI (≥2)	164 (153)	95.5* (78.8)	134 (124)	94.0* (79.1)	470 (351)	96.9 (55.9)	344 (148)	92.4* (24.6)	0.1136 (<0.0001)	1,112 (338)	94.7* (47.5)
For RT only	3	3.0*	1	1.5*	5	1.7*	3	0.7*	.	12	1.4*
Computer use for RT recording	63	95.5*	62	92.5*	263	90.7*	238	82.4*	0.0015	626	87.9*

Abbreviations: CT = computed tomography; RTP = radiotherapy planning; MRI = magnetic resonance imaging; other abbreviations as in Table 2.
* Percentage of institutions that have equipment (≥2 pieces of equipment per institution).

individual identification on staffing data. Finally, there were 907 nurses and clerks.

Distributions of primary sites, specific treatment and palliative treatment

Table 5 lists the distribution of primary sites by institutional stratification. The most common disease site was the breast, followed by lung/bronchus/mediastinum and genitourinary. In Japan, the number of patients with prostate cancer undergoing RT was approximately 13,200 in 2005, but the number has been increasing most rapidly. The stratification of institutions indicated that more patients with lung cancer were treated at the nonacademic institutions (B1 and B2), and more patients with head-and-neck cancer were treated at academic institutions (A1 and A2; $p < 0.0001$).

Table 6 lists the distribution of use of specific treatment and the number of patients treated with these modalities by the PCS stratification of institutions. Brachytherapy, such as intracavitary RT, interstitial RT, and radioactive iodine therapy, for prostate cancer was used more frequently in academic institutions than in nonacademic institutions ($p < 0.0001$). Similar trends were observed for other specific treatments such as total body RT, intraoperative RT, stereotactic brain RT, stereotactic body RT, IMRT, thermoradiotherapy, and RT of the pterygium by ^{90}Sr. In 2005, 4.6% of patients ($n = 755$) were treated with IMRT at 33 institutions. This percentage was significantly lower than that of institutions using linear accelerators with IMRT function (22%; Table 2).

Table 7 lists the number of patients with any type of brain metastasis or bone metastasis treated with RT according to the same institutional stratification. B1 institutions treated more patients with brain metastasis (11% of all patients) than other types of institutions ($p < 0.0001$), and the use of RT for bone metastasis ranged from 11% for A1 to 19% for B2 ($p < 0.0001$). Overall, more patients were treated with RT at nonacademic type B2 institutions than at A1 or A2 institutions.

Geographic patterns

Figure 3 shows the geographic distributions of the annual number of patients (new plus repeat) per 1,000 population by 47 prefectures arranged in order of increasing number of JASTRO-certified physicians per 1,000,000 population (14). Significant differences were found in the use of RT, from 0.9 patients/1,000 population (Saitama and Okinawa) to 2.1 (Hokkaido). The average number of patients/1,000 population per quarter ranged from 1.37 to 1.57 ($p = 0.2796$). A tendency was found for a greater number of JASTRO-certified physicians to be accompanied by an increased use of RT for cancer patients, although the correlation was not statistically significant. The use rate of RT in a given prefecture was not necessarily related to its population density in 2005, just as we observed in the 1990 data (3).

DISCUSSION

In 1990, fewer facilities for RT were available and fewer patients were treated with RT in Japan than in the United States. However, the numbers for Japan improved

Table 4. Structure and personnel by PCS institutional stratification

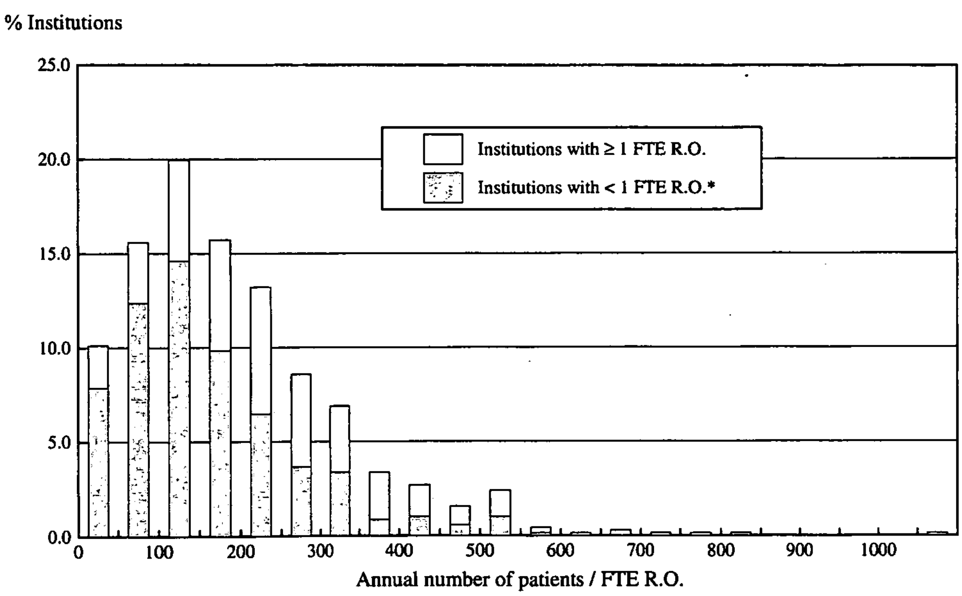
	Structure and personnel					
	A1 (*n* = 66)	A2 (*n* = 67)	B1 (*n* = 290)	B2 (*n* = 289)	*p-value*	Total (*n* = 712)
Institutions/total institutions (%)	9.3	9.4	40.7	40.6		100
Institutions with RT bed (*n*)	57 (86.4)	35 (52.2)	127 (43.8)	68 (23.5)		287 (40.3)
Average RT beds/institution (*n*)	14.0	4.8	3.4	1.0		3.6
JASTRO-certified RO (full time)	181	62	139	44		426
Average JASTRO-certified RO/institution (*n*)	2.7	0.9	0.5	0.2	<0.0001	0.6
Total (full-time and part-time) RO FTE*	290.9	95.55	258.77	129.24		774.46
Average FTE ROs/institution	4.41	1.43	0.89	0.45	<0.0001	1.09
Patient load/FTE RO	188.7	224.1	343.0	202.1	<0.0001	246.8
Total RT* technologists	388.6	176.3	637.7	431.9		1634.5
Average technologists/institution (*n*)	5.9	2.6	2.2	1.5	<0.0001	2.3
Patient load/RT technologist	141.2	121.5	139.2	60.5	<0.0001	117.0
Total nurses/assistants/clerks (*n*)	202.2	92.4	390.55	221.8		907
Full-time medical physicists + part-time (*n*)	51 + 10.1	8 + 7	39 + 7	19 + 6		117 + 30.1
Full-time RT QA staff + part-time	81 + 0	31 + 7	102.5 + 3	42.3 + 3		256.8 + 13

Abbreviations: JASTRO = Japanese Society of Therapeutic Radiation Oncology; RO = radiation oncologist; FTE = full-time equivalent (40 h/wk only for RT practice); QA = quality assurance; other abbreviations as in Table 2.

Data in parentheses are percentages.

significantly during the next 15 years, with respective increases by factors of 2 and 2.6 compared with those in 1990 (3). However, the use rate of RT for new cancer patients remained at 25%, less than one-half the ratio in the United States and European countries. The anticancer law was enacted in Japan to promote RT and education for ROs, as well as medical physicists or other staff members, from April 2006. For the implementation of this law, comparative data of the structure of radiation oncology in Japan and the United States, as well as relevant PCS data, proved helpful. Because the increase in the elderly population of developed countries is the greatest in Japan, RT is expected to play an increasingly important role.

Compared with 1990, the number of linear accelerator systems increased significantly by 2.3 times, and the percentage of systems using telecobalt decreased to 7%. Furthermore, the functions of linear accelerators, such as dual energy, three-dimensional conformal RT (multileaf collimator width <1 cm), and IMRT improved. The number of high-dose-rate RALS in use increased by 1.4 times and the use of



* Number of .FTEs for institutions with FTE<1 was calculated as FTE=1 to avoid overestimating pateint' load/R.O.

Fig. 1. Percentage of institutions by patient load/full-time equivalent (FTE) staff of radiation oncologists (RO) in Japan. White bars represent institutions with one or more FTE staff, and gray bars represent institutions with fewer than one FTE radiation oncologist. Each bar represents interval of 50 patients/FTE radiation oncologist.

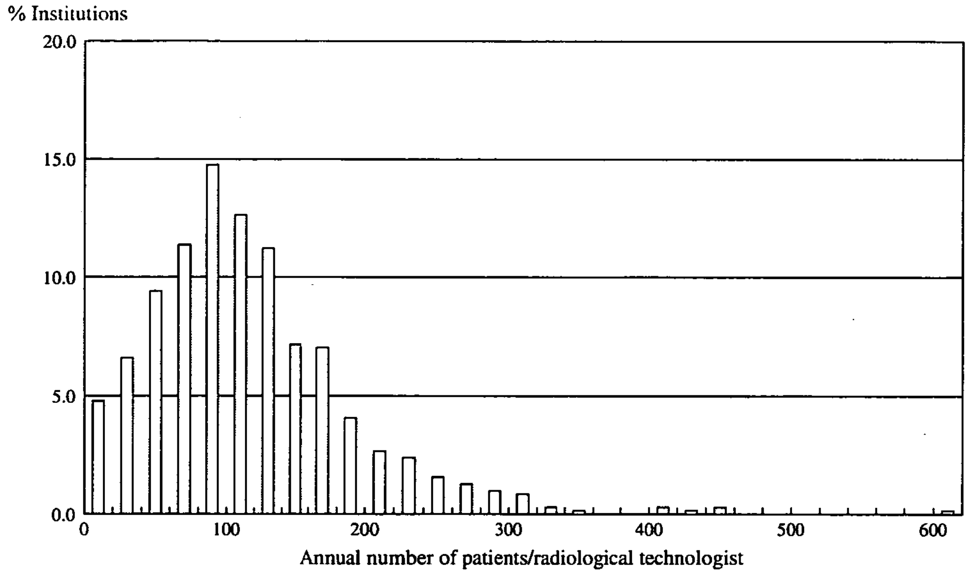


Fig. 2. Percentage of institutions by patient load/radiotherapy technologist in Japan. Each bar represents interval of 20 patients/full-time equivalent staff.

^{60}Co-RALS has largely been replaced by ^{192}Ir-RALS. CT simulators were installed in 55% of institutions nationwide, and RT planning systems were used in 93%, for an increase in the number of RT planning systems of 4.87 times. The maturity of the functions of linear accelerator and greater possession rates of CT simulators and systems using ^{192}Ir-RALS were closely related to the institutional stratification by PCS, which could therefore aid in the accurate discrimination of structural maturity and immaturity and the identification of structural targets to be improved. The Japanese PCS group published structural guidelines based on the PCS data (16), and we plan to use this structural data for a new PCS to revise the Japanese structural guidelines.

The staffing patterns in Japan also improved in terms of numbers. However, the institutions that had fewer than one FTE RO on their staff still accounted for >60% nationwide, and this rate did not change during the 15 years from 1990 to 2005. In Japan, most institutions still rely on part-time ROs. First, the number of cancer patients who require RT is increasing more rapidly than the number of ROs. Second, specialist fees for ROs in academic institutions are not recognized by the Japanese medical care insurance system, which is strictly controlled by the government. Most ROs must therefore work part-time at affiliated hospitals in the B1 and B2 groups to earn a living. Thus, to reduce the number of institutions that rely on part-time ROs and might encounter

Table 5. Primary sites of cancer treatment with RT in 2005 by PCS institutional stratification for new patients

	A1 (*n* = 65)		A2 (*n* = 67)		B1 (*n* = 285)		B2 (*n* = 284)		Total (*n* = 701)	
Primary site	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Cerebrospinal	2,603	5.6	770	4.5	4,431	6.4	795	3.6	8,599	5.6
Head and neck (including thyroid)	6,318	13.7	2,372	13.9	6,033	8.7	1,650	7.5	16,373	10.6
Esophagus	3,164	6.9	1,171	6.9	4,426	6.4	1,452	6.6	10,213	6.6
Lung, trachea, and mediastinum	7,069	15.3	2,639	15.5	14,946	21.5	5,386	24.6	30,040	19.4
Lung	5,469	11.8	2,272	13.3	12,917	18.6	4,734	21.6	25,392	16.4
Breast	8,945	19.4	3,049	17.9	14,148	20.4	4,119	18.8	30,261	19.6
Liver, biliary tract, pancreas	1,936	4.2	713	4.2	2,742	3.9	964	4.4	6,355	4.1
Gastric, small intestine, colorectal	1,897	4.1	806	4.7	3,742	5.4	1,399	6.4	7,844	5.1
Gynecologic	3,253	7.0	1,156	6.8	3,405	4.9	855	3.9	8,669	5.6
Urogenital	5,544	12.0	2,043	12.0	8,068	11.6	2,905	13.3	18,560	12.0
Prostate	4,290	9.3	1,385	8.1	5,627	8.1	1,916	8.8	13,218	8.6
Hematopoietic and lymphatic	2,460	5.3	1,052	6.2	3,624	5.2	904	4.1	8,040	5.2
Skin, bone, and soft tissue	1,607	3.5	749	4.4	1,830	2.6	1,018	4.6	5,204	3.4
Other (malignant)	705	1.5	235	1.4	822	1.2	313	1.4	2,075	1.3
Benign tumors	664	1.4	268	1.6	1,289	1.9	135	0.6	2,356	1.5
Pediatric <15 y (included in totals above)	435	0.9	123	0.7	187	0.3	302	1.4	1,047	0.7
Total	46,165	100	17,023	100	69,506	100	21,895	100	154,589†	(100)

Abbreviations as in Table 2.
*Number of total number of new patients different with these data, because no data on primary sites were reported by some institutions.

Table 6. Distribution of specific treatments and numbers of patients treated with these modalities by PCS stratification of institutions

	A1 (n = 66)		A2 (n = 67)		B1 (n = 290)		B2 (n = 289)			Total (n = 712)	
Specific therapy	n	%	n	%	n	%	n	%	p	n	%
Intracavitary RT (n)									<0.0001		
Treatment facilities	61	92.4	37	55.2	71	24.5	12	4.2		181	25.4
Cases	1,670		527		974		75			3,246	
Interstitial RT									<0.0001		
Treatment facilities	42	63.6	14	20.9	18	6.2	5	1.7		79	11.1
Cases	1,818		286		638		31			2,773	
Radioactive iodine therapy for prostate cancer									<0.0001		
Treatment facilities	25	37.9	6	9.0	7	2.4	1	0.3		39	5.5
Cases	1,166		152		430		17			1,765	
Total body RT									<0.0001		
Treatment facilities	60	90.9	36	53.7	78	26.9	17	5.9		191	26.8
Cases	706		237		687		108			1,738	
Intraoperative RT									<0.0001		
Treatment facilities	23	34.8	12	17.9	20	7.0	11	3.8		66	9.3
Cases	212		39		111		25			387	
Stereotactic brain RT									<0.0001		
Treatment facilities	46	69.7	31	46.3	91	31.4	29	10.0		197	27.7
Cases	1,680		482		8,513		447			11,122	
Stereotactic body RT									<0.0001		
Treatment facilities	31	50.0	14	20.9	36	12.4	11	3.8		92	12.9
Cases	482		263		679		234			1,658	
IMRT									<0.0001		
Treatment facilities	16	24.2	4	6.0	12	4.1	1	0.3		33	4.6
Cases	426		67		212		50			755	
Thermoradiotherapy									0.0004		
Treatment facilities	10	15.2	4	6.0	15	5.2	7	2.4		36	5.1
Cases	339		27		134		81			581	

Abbreviations: PCS = Patterns of Care Study; RT = radiotherapy; IMRT = intensity-modulated radiotherapy.

problems with their quality of care, a drastic reform of our current medical care systems is required. However, great care is needed to ensure that the long-term success of radiation oncology in Japan and patient benefits are well balanced with the costs. Even under the current conditions, however, the number of FTE ROs increased by 2.1 times compared with the number in 1990 (3). However, the patient load/FTE RO also increased by 1.4 times to 247 during the same period, perhaps reflecting the growing popularity of RT because of recent advances in technology and improvement in clinical results. This caseload ratio in Japan has already exceeded the limit of the Blue Book guidelines of 200 patients/RO (15, 16). The percentage of distribution of institutions by patient load/RO showed a slightly smaller distribution than that of the United States in 1989 (3). Therefore, Japanese radiation oncology seems to be catching up quickly with the western system despite limited resources. Furthermore, additional recruiting and education of ROs are now top priorities of the JASTRO.

The distribution of patient load/RT technologists showed that 13% of institutions met the narrow guideline range (100–120/RT technologist), and the rest were densely distributed around the peak. Compared with the distribution in the United States in 1989, >20% of institutions in Japan had a relatively low caseload of 10–60 because a large number of smaller B2-type institutions still accounted for nearly 40% of institutions exceeding the range of the guidelines. As for medical physicists, a similar analysis for patient load/FTE staff was difficult, because the number was still small, and they were working mainly in metropolitan areas. In Japan, radiation technologists have been acting as medical physicists, so that their education has been changed from 3 to 4 years

Table 7. Brain metastasis or bone metastasis patients treated with RT in 2005 by PCS institutional stratification

	Patients					
Metastasis	A1 (n = 66)	A2 (n = 67)	B1 (n = 290)	B2 (n = 289)	p	Total (n = 712)
Brain	2,565 (4.7)	1,204 (5.6)	9,774 (11.0)	1,778 (6.8)	<0.0001	15,321 (8.0)
Bone	6,243 (11.4)	2,845 (13.3)	13,331 (15.0)	5,057 (19.4)	<0.0001	27,476 (14.4)

Data presented as number of patients, with percentages in parentheses.

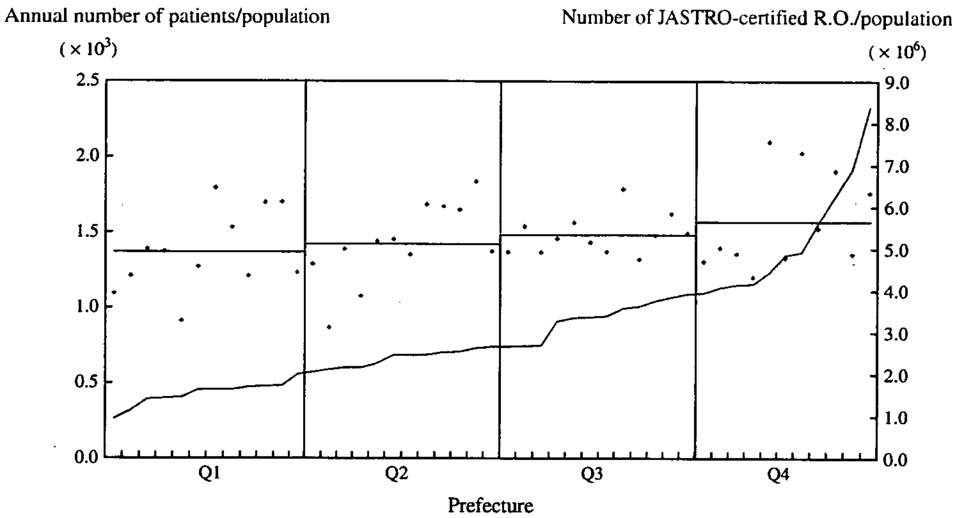


Fig. 3. Geographic distribution for 47 prefectures of annual number of patients (new plus repeat) per 1,000 population arranged in order of increasing number of Japanese Society of Therapeutic Radiation Oncology (JASTRO)-certified radiation oncologists (RO)/1,000,000 population by prefecture. Q1, 0–25%; Q2, 26–50%; Q3, 51–75%; and Q4, 76–100%. Horizontal bar shows average annual number of patients (new plus repeat) per 1,000 population of prefectures per quarter.

during the past decade and graduate and postgraduate courses have been introduced. Currently, those who have obtained a master's degree or radiation technologists with enough clinical experience can take the examination for qualification as a medical physicist, as can those with a master's degree in science or engineering, like those in the United States or Europe. In Japan, a unique education system for medical physicists might be developed because the anticancer law actively supports improvements in quality assurance/quality control specialization for RT. However, the validity of this education and training system remains unsatisfactory, because we are still in the trial-and-error stage.

The distribution of the primary site for RT showed that more lung cancer patients were treated in B1 or B2 nonacademic institutions and more head-and-neck cancer patients were treated in A1 or A2 academic institutions. These findings might be because more curative patients were referred to academic institutions and more palliative patients with lung cancer were treated in nonacademic institution in Japan. In addition, more patients with bone metastasis were treated in nonacademic institutions. The use of specific treatments and the number of patients treated with these modalities were significantly affected by institutional stratification, with more specific treatments performed at academic institutions. These findings indicate that significant differences in the patterns of care, as reflected in the structure, process, and, possibly, outcomes for cancer patients still exist in Japan. These differences point to opportunities for improvement. We, therefore, based the Japanese Blue Book guidelines on this stratification by the PCS data (16) and are now in preparing to revise them accordingly.

The geographic patterns demonstrated significant differences among the prefectures in the use of RT, ranging from 0.9 to 2.1 patients/1,000 population. Furthermore, the number of JASTRO-certified physicians/population might be associated with the use of RT, so that a shortage of ROs or medical physicists on a regional basis will remain a major concern in Japan. The JASTRO has been making every effort to recruit and educate ROs and medical physicists through public relations, training courses, involvement in the national examination for physicians, and seeking to increase the reimbursement by the government-controlled insurance program, and other actions.

CONCLUSION

The Japanese structure of radiation oncology has clearly improved during the past 15 years in terms of equipment and its functions, although a shortage of manpower and differences in maturity by type of institution and caseload remain. Structural immaturity is an immediate target for improvement, and, for improvements in process and outcome, the PCS or National Cancer Database, which are currently operational and being closely examined, can be expected to play an important role in the future.

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CLINICAL INVESTIGATION

CHANGES IN PATTERNS OF CARE FOR LIMITED-STAGE SMALL-CELL LUNG CANCER: RESULTS OF THE 99-01 PATTERNS OF CARE STUDY—A NATIONWIDE SURVEY IN JAPAN

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Background: This study was undertaken to analyze the practice process of thoracic radiotherapy (TRT) and evaluate changes in patterns of care for patients with limited-stage small-cell lung cancer (LS-SCLC) in Japan.
Methods and Materials: The Patterns of Care Study (PCS) conducted the second nationwide survey of care process for patients with LS-SCLC treated by using TRT between 1999 and 2001.
Results: The PCS collected data for 139 patients with LS-SCLC (man-woman ratio, 5:1; median age, 69 years; age > 70 years, 43%; Karnofsky Performance Status > 70, 73%; and Stage III, 88%). Median total dose was 50 Gy. Twice-daily TRT was used in 44% of patients. Median field size was 12 × 14 cm. The most commonly used photon energy was 10 MV (77%), whereas obsolete techniques using ^{60}Co or X-ray energy less than 6 MV comprised 12%. Three-dimensional conformal therapy was used with 12% of patients. Computed tomography simulation was performed in 40% of cases. Only 12 patients (8.6%) received prophylactic cranial irradiation (PCI). Concurrent chemotherapy and TRT (CCRT) was used for 94 patients (68%). Only 6 patients (4.4%) entered clinical trials. Compared with the previous PCS 95-97, significant increases in the use of CCRT (34–68%; $p < 0.0001$), twice-daily TRT (15–44%; $p < 0.0001$), and PCI (1.7–8.6%; $p = 0.0045$) were observed, although the absolute number of patients receiving PCI was still extremely low.
Conclusions: Evidence-based CCRT and twice-daily TRT has penetrated into clinical practice. However, PCI is not yet widely accepted in Japan.

Patterns of Care Study, Small-cell lung cancer, Thoracic radiation therapy, Nationwide survey, Practice process.

INTRODUCTION

The Patterns of Care Study (PCS) is a retrospective study designed to investigate the national practice processes for selected malignancies during a specific period (1). In addition to documenting practice processes, the PCS is important in developing and spreading national guidelines for cancer treatment. In Sept 1998, the Japanese PCS conducted the first nationwide survey for patients with lung cancer treated using thoracic radiotherapy (TRT) between 1995 and 1997 (PCS 95-97). The main findings from the PCS 95-97 are summarized as follows. First, the use of TRT for patients with limited-stage small-cell lung cancer (LS-SCLC) in Japan is predominantly influenced by institutional characteristics, rather than age group. Second, patient age significantly influenced the use of chemotherapeutic modality, such as etoposide and cisplatin for patients with LS-SCLC (2, 3).

Because results of several key clinical studies of patients with LS-SCLC were reported between 1997 and 1999, it seems meaningful to evaluate whether practice processes in Japan were changed accordingly. The second PCS for lung cancer investigated patient characteristics, workup studies, the process of TRT, and use of chemotherapy in patients with LS-SCLC treated by using TRT between 1999 and

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2001. The objectives of the present study are as follows. First, compile processes in TRT for patients with LS-SCLC treated between 1999 and 2001, and second, compare patient characteristics and treatment modalities between the PCS 95-97 and PCS 99-01 in Japan.

METHODS AND MATERIALS

Between July 2002 and August 2004, the PCS conducted a second national survey of radiation therapy for patients with lung cancer in Japan. The Japanese PCS developed an original data format for patients with lung cancer. The PCS performed an extramural audit survey for 73 (38 academic and 35 nonacademic institutions) of 556 institutions by using stratified two-stage cluster sampling and collected data for 768 eligible patients with lung cancer. Data collection consisted of two steps of random sampling. Before random sampling, all institutions were classified into one of four groups. Criteria for stratification were described elsewhere (2, 4). Briefly, the PCS stratified Japanese institutions as follows: A1, such academic institutions as university hospitals or national/regional cancer center hospitals treating 430 or more patients per year; A2, academic institutions treating fewer than 430 patients; B1, nonacademic institutions treating 130 or more patients per year; and B2, those treating fewer than 130 patients per year. Cutoff values for numbers of patients treated per year between A1 and A2 institutions and B1 and B2 institutions were increased from those used in the previous PCS because of the increase in number of patients treated using radiation therapy in Japan (4).

Eligible patients included those with 1997 International Union Against Cancer Stages I–III lung cancer treated by using TRT between 1999 and 2001, with Karnofsky Performance Status (KPS) greater than 50 before the start of treatment and no evidence of other malignancies within 5 years. The International Union Against Cancer staging system was used because the PCS comprehensively surveyed patients with non-SCLC and those with SCLC. As mentioned, Stages I–III SCLC do not precisely match the definition of LS-SCLC by Mountain (5). However, no definition of this term has been universally accepted. The PCS survey of TRT charts showed that for patients with SCLC, the tumor could be encompassed within the TRT field. Thus, in the present study, all patients were regarded as having LS-SCLC.

The aims of this study are to provide patterns of practice concerning: (*1*) patient background; (*2*) workup studies; (*3*) TRT, including photon energies, total dose, spinal cord dose, field arrangements, prescription point, and use of prophylactic cranial irradiation (PCI); and (*4*) chemotherapy, including agents, number of chemotherapy cycles, sequence of chemotherapy, and TRT. Patient background included demographics and medical status, such as KPS, comorbidities, stage, and whether treated on an outpatient basis. In addition, practice patterns of the PCS 99-01 were compared with those of the PCS 95-97.

To validate the quality of collected data, the PCS used the Internet mailing list among all the surveyors. *In situ* real-time check and adjustment of the data input were available between each surveyor and the PCS committee. In tables, "missing" indicates that the item in the data format was left empty, whereas "unknown" means that the item in the format was completed with data unknown. We combined missing and unknown in tables because their meanings were the same in most cases; no valid data were obtained in the given resources. Cases with unknown values were included when both percentage and significance values were calculated. Statistical significance was tested by using chi-square test. A $p < 0.05$ was considered statistically significant. Overall survival, assessed from the first day of radiation therapy, was estimated by using the Kaplan-Meier product-limit method, and differences were evaluated using log-rank test.

RESULTS

Patient backgrounds

There were 141 patients with SCLC, which constituted 18% of all patients with lung cancer surveyed. Of those, 2 patients underwent initial surgical resection and adjuvant postoperative irradiation. Thus, in the present study, the PCS analyzed the remaining 139 patients who did not undergo surgery (Table 1).

There were 116 men and 23 women with an age range of 36–85 years (median, 69 years). Patients older than 70 years constituted 43% of the patient population. For that elderly patient pool, the institutional breakdown was as follows: 31% in A1, 39% in A2, 50% in B1, and 50% in B2 ($p = 0.037$). For comorbidities, the most frequent adverse medical conditions were cardiovascular disease (34%) and diabetes (14%). Seventy-three percent had KPS of 80% or greater. Comparison of four institutional groups failed to show differences in terms of patient background other than patient age and KPS. Patients with KPS of 80 or greater comprised 89% of A1, 55% of A2, 74% of B1, and 65% of B2 strata ($p = 0.0071$). A majority of patients (88%) had Stage III disease. There were no significant differences in distributions of T and N classifications or clinical stages between institutional groups. Only 5% of all patients were treated on an outpatient basis.

Workup studies

Workup studies are listed in Table 2. Pretreatment workup included chest computed tomography (CT) in 96%, bronchoscopy in 93%, brain CT or magnetic resonance imaging in 86%, and bone scan in 79% of surveyed patients. Chest/abdominal CT and bone scan were used for a majority of patients, whereas positron emission tomography (PET) was used for an extremely small number of patients. Comparison of four institutional groups failed to show differences in terms of workup studies.

Practice process of TRT

Thoracic radiotherapy methods are listed in Table 3. Median total dose of TRT was 50 Gy, and median field size was 12 × 14 cm. Median dose to the spinal cord was 42 Gy. A CT simulator was used for planning in 40% of patients. Three-dimensional conformal therapy was used in 12%. The planning target volume included the ipsilateral hilus in 96%, ipsilateral mediastinum in 96%, contralateral mediastinum in 84%, contralateral hilus in 17%, ipsilateral supraclavicular region in 25%, and contralateral supraclavicular region in 15%. Field reduction during the course of TRT was done for 61%. Twice-daily radiotherapy was used for 44%. Photon energy generally was 10 MV (77%), whereas obsolete techniques using ^{60}Co or X-ray energy less than 6 MV were used for 12%. Only 12 patients (8.6%) received PCI. Median dose of PCI was 25 Gy. Only 6 patients (4.4%) entered clinical trials.

Table 1. Patient and tumor characteristics

Characteristics	Stratification of institutions A1	A2	B1	B2	Total	p-value
No. of patients	36	23	54	26	139	
Age (y)						0.037
Range	44–85	36–81	40–81	54–85	36–85	
Median	69	68	71	71	69	
>70 (%)	31	39	50	50	43	
Sex						0.780
Men	30	18	47	21	116	
Women	6	5	7	5	23	
Karnofsky performance status						0.013
≥80 (%)	89	55	74	65	73	
Clinical stage/UICC 1997						0.475
I	0	1	2	2	5	
IIA, IIB	3	3	4	1	11	
IIIA	10	6	19	10	45	
IIIB	23	13	28	13	77	
Unknown/missing	0	0	1	0	1	
T classification						0.569
T1–2	14	11	25	14	64	
T3–4	22	12	28	12	74	
Unknown/missing	0	0	1	0	1	
N classification						0.551
N0–1	7	4	9	6	26	
N2–3	29	19	44	20	112	
Unknown/missing	0	0	1	0	1	

Abbreviation: UICC = International Union Against Cancer.

Institutional stratification influenced several radiotherapeutic parameters (Table 4). Photon energy of 6 MV or greater was used for 97% of patients in A1, 96% in A2, 87% in B1, and 69% in B2 institutions ($p = 0.0006$). The ^{60}Co machines were not used in any A1 to B1 institutions. Twice-daily radiotherapy was used for 57 of 113 patients in A1 to B1 institutions, but only 4 of 26 patients in B2 institutions were treated in that manner ($p = 0.0012$). The PCI was used for 7 of 36 patients (19%) in A1 institutions, but only 5 patients (4.9%) in the remaining institutions ($p = 0.0073$). Use of a CT simulator was more frequent in A1 (52%) and A2 (65%) compared with B1 (34%) and B2 (17%) institutions ($p = 0.011$).

One hundred twenty-nine patients (93%) received systemic chemotherapy. Of those, platinum-based chemotherapy constituted 98%. Concurrent chemotherapy and TRT (CCRT) was used for 68% (73% of patients who received systemic chemotherapy). Median number of chemotherapy cycles was four. Median times from the first day of systemic chemotherapy to the first date and last date of TRT were 3 and 44 days, respectively. Proportions of patients who received chemotherapy were 97% in A1, 96% in A2, 91% in B1, and 89% in B2 institutions ($p = 0.49$).

Comparison between two PCS studies

Patient backgrounds and practice patterns in PCS 99-01 were compared with those in PCS 95-97. Differences between the two studies are listed in Table 5. Based on two-stage cluster sampling, the ratios of academic to nonacademic institutions were almost equal in the two surveys. Although median age in PCS 99-01 was slightly older than that in PCS 95-97, patients' backgrounds were similar in the studies. Use of obsolete treatment equipment (photon energy < 6 MV and ^{60}Co) decreased from 20% in PCS 95-97 to 12% in PCS 99-01 ($p = 0.06$). The greatest differences were seen in the use of twice-daily TRT and CCRT. Twice-daily TRT increased from 15% in PCS 95-97 to 44% in PCS 99-01 ($p < 0.0001$). Use of CCRT in PCS 99-01 was twice as high as in PCS 95-97 (68% vs. 34%; $p < 0.0001$). Although a significant increase in the use of PCI was observed (1.7–8.6%; p = 0.0045), the rate was still extremely low in Japanese practice.

Table 2. Percentage of patients examined by using each diagnostic technique in the course of staging

Chest CT	96%
Chest MRI	7%
Bronchoscope	93%
Bone scan	79%
Abdominal CT	88%
Positron emission tomography	2%
Brain CT or MRI	86%

Abbreviations: CT = computed tomography; MRI = magnetic resonance imaging.

Table 3. Process of thoracic radiation therapy for patients with limited-stage small-cell lung cancer

Median total dose (Gy)	50
Median spinal cord dose (Gy)	42
Use of CT simulator (%)	40
Three-dimensional conformal therapy (%)	12
Beam energy (%)	
^{60}Co	1.4
<6 MV	10.8
≥6 MV	88
Median field size (cm)	12 × 14
Field reduction during treatment (%)	61
IRB-approved protocol treatment (%)	4.4
Twice-daily radiotherapy (%)	44
Prophylactic cranial irradiation (%)	8.6
Area included in planning target volume (%)	
Ipsilateral hilus	96
Ipsilateral mediastinum	96
Contralateral mediastinum	84
Contralateral hilus	17
Ipsilateral supraclavicula	25
Contralateral supraclavicula	15
Systemic chemotherapy (%)	93
Concurrent chemotherapy and thoracic radiotherapy (%)	68

Abbreviations: CT = computed tomography; IRB = institutional review board.

Comparison of preliminary outcomes between studies

There are known limitations in survival analyses in this type of retrospective survey study. Still, preliminary outcome data in the two studies could be compared. Overall survival rates of the entire patient pool in each study are shown in Fig. 1. Two-year survival rates in PCS 95-97 and PCS 99-01 were 34% and 45%, with a median follow-up of only 11 months in both studies, respectively. Median survival times of the patient pools in PCS 95-97 and PCS 99-01 were 14 and 17 months, respectively. These differences did not reach a statistically significant level.

Table 4. Process of thoracic radiation therapy influenced by institutional stratification

	Stratification of institutions					
Characteristics	A1	A2	B1	B2	Total	p-value
Photon energy						0.0006
^{60}Co	0	0	0	2	2	
<6 MV	1	1	7	6	15	
≥6 MV	35	22	47	18	122	
Twice-daily fractionation used						0.0012
Yes	18	11	28	4	61	
No	18	12	26	22	78	
Treatment planning						0.011
Use of CT simulator (%)	52	65	34	17	40	
Prophylactic cranial irradiation used						0.0002*
Yes	7	2	3	0	12	
No	29	17	48	24	118	
Unknown/missing	0	4	3	2	9	

Abbreviation: CT = computed tomography.
* A1 vs. A2–B2; $p = 0.0073$.

Table 5. Comparison of treatment modalities between two studies

Background and treatment process	PCS 95-97 (n = 174)	PCS 99-01 (n = 139)
SCLC/all lung cancer (%)	16	18
Median age (y)	65	69
KPS > 70 (%)	70	73
Stage III (%)	87	88
Median total dose (Gy)	50	50
Photon energy <6 MV or ^{60}Co (%)	20	12
Use of CT-simulator (%)	NA	40
Twice-daily thoracic radiotherapy (%)*	15	44
Chemotherapy used (%)	92	93
Concurrent chemoradiation (%)†	34	68
Prophylactic cranial irradiation (%)‡	1.9	8.6
Survival at 2-years (%)	34	45

Abbreviations: PCS = Patterns of Care Study; SCLC = small-cell lung cancer; KPS = Karnofsky Performance Status; CT = computed tomography; NA = not available.
* $p < 0.0001$ by chi-square test.
† $p < 0.0001$ by chi-square test.
‡ $p = 0.0045$ by chi-square test.

DISCUSSION

Results of the present PCS reflect national treatment trends for TRT for patients with LS-SCLC in Japan between 1999 and 2001. Through this second nationwide audit survey and data analysis, PCS established the general patterns of care for patients with LS-SCLC in Japan. Results also show the influence of the structure of radiation oncology on the process of TRT and how state-of-the-art cancer care supported by clinical trial results has penetrated into the national practice process during the study period.

During the study period, TRT for LS-SCLC constituted less than one fifth of all radiation therapy for patients with lung cancer. This result was similar to data from the United States (6). Use of such staging studies as chest CT, bone scan, and PET scan for patients with SCLC was in line with guidelines (7) and very similar to the report from the United States (6). A PET scan in clinical use was still scarce. Only a small fraction of patients participated in clinical trials similar to those observed in the United States. In Japan, twice-daily TRT was used more frequently and PCI was used less frequently compared with the United States. However, it should be noted that subjects of the PCS in the United States were treated between 1998 and 1999, preceding the results of key studies that supported the use of twice-daily radiation therapy and PCI.

The study shows that more suitable photon energies were used in TRT at academic institutions. Thirty-one percent of patients in B2 institutions were treated with a linear accelerator with less than 6 MV or a ^{60}Co machine that did not meet the standard of care for equipment to treat patients with lung

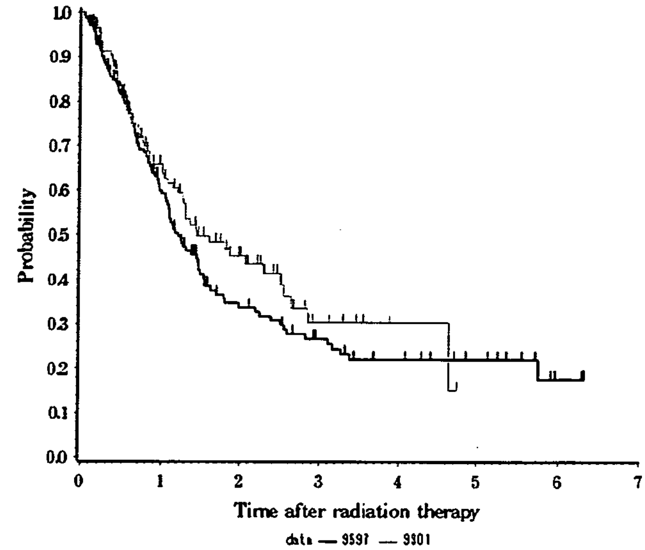

Fig. 1. Kaplan-Meier estimate of overall survival of patients with Stages I–III small-cell lung cancer surveyed in the 1995–1997 (dark line) and 1999–2001 (bright line) Patterns of Care Studies in Japan

cancer, although this rate decreased from PCS 95-97 (>40% in B2) and was somewhat favorable compared with postoperative radiation therapy for patients with lung cancer in the same period (8). The availability of CT simulators was greater than 50% in academic institutions, but only one third in B1 and even lower in B2 institutions. In modern radiation therapy, CT-based treatment planning is essential for TRT to achieve optimal target coverage while reducing the dose to normal tissue. Twice-daily TRT was used more frequently for patients in A1 to B1 institutions than patients in B2 institutions. The PCI was used for 19% of patients in A1 institutions, but only 4.9% of patients in the remaining institutions. Although the general quality of radiation oncology improved from PCS 95-97, results of the present study show that institutional stratification still influences the structure and process of radiotherapy, such as availability of CT simulators, the flexibility of external beam energy selection, and use of evidence-based cancer care in Japan.

During the past 20 years, survival prolongation in patients with LS-SCLC was attained mainly by clinical trials that studied some aspect of radiation therapy, such as integration of TRT (9, 10), optimization of timing and fractionation of TRT (11), and introduction of PCI (12). The TRT is an essential component of the standard management of patients with LS-SCLC. Two meta-analyses showing the advantage of the addition of TRT to systemic chemotherapy, published in 1992 (9, 10), preceded our first national survey (PCS 95-97). In PCS 99-01, although 43% of all surveyed patients were older than 70 years and 23% of all patients had KPS of 70% or less, 93% of all patients received chemotherapy. This percentage is very similar to that in PCS 95-97 (2, 3).

When interpreting our data, it is important to note that they are limited to patients who received TRT as part of their overall treatment regimen. However, these two surveys showed that use of systemic chemotherapy was reasonably high in Japanese practice. Based on several studies published during the past 10 years, CCRT up front has emerged as a standard of care generating the highest survival rates (11, 13, 14). A landmark study supporting twice-daily TRT was published in 1999 after the previous PCS 95-97 (11). In that study, Turrisi *et al.* (11) showed a significant benefit in 5-year survival rate with the use of twice-daily TRT (45 Gy in 1.5 Gy fractions twice daily) concurrent with chemotherapy compared with once-daily TRT (45 Gy in 1.8 Gy fractions every day). Use of CCRT in PCS 99-01 (68%) was twice as high as in PCS 95-97 (34%). Similarly, there was a notable increase in the use of twice-daily TRT after PCS 95-97. In the present study, 44% of patients received twice-daily TRT, nearly three times as high as in PCS 95-97. Although it is still unclear whether twice-daily TRT to 45 Gy in 3 weeks is superior to a higher total dose of 60–70 Gy delivered by using more standard fractionation, it seems that diffusion of twice-daily TRT to Japanese practitioners was rapid. It seems likely that the marked increase in use of twice-daily TRT with concurrent chemotherapy in Japan contributed to the widespread use (95%) of inpatient treatment in PCS 99-01. In general, once-daily treatment is better accepted for outpatient care, whereas twice-daily scheduling is convenient for the care of inpatients, but at greater cost. Marked increases in the use of CCRT and twice-daily TRT indicates greater acceptance of these treatment modalities by radiation oncologists across Japan.

However, PCI has yet to be systematically adopted in Japanese practice. Despite the 1999 publication of another landmark trial that showed the survival advantage of PCI for complete responders (12), only 8.6% of all patients received this intervention. At the time of PCS 95-97, the role of PCI had not been established and it was used for only 1.9% of all patients (2). Before the present survey, it was expected that the percentage of patients who received PCI would be greater on the basis of the meta-analysis. Although a slight increase in use of PCI was observed, the rate was still extremely low in Japan. Information about the number of complete responders was outside the audit. However, a complete response rate of at least 50% is expected for study subjects (15). Whether this is caused by the small number of radiation oncologists in Japan or the small number of patients who received radiation therapy for cancer treatment is unknown. We reported previously that the number of full-time radiation oncologists is low, especially in nonacademic institutions in Japan (2). According to cancer statistics in Japan, radiation therapy was used for only 11.3% of all patients with cancer in 1999 compared with medical (27.5%) and surgical treatment (69.9%) (16). It is not clear why evidence-based PCI has not yet been widely accepted in Japan as opposed to the rapid diffusion of CCRT and twice-daily TRT in clinical practice. It appears that physicians in Japan hesitate to use PCI, and their patients are reluctant to receive PCI even if it is beneficial. Results of the ongoing third national survey in Japan will be particularly interesting in this regard.