次々と明らかとなるなど，まさに日進月歩である．また，新しい治療薬も次々と開発されてきており，B型肝炎の診療は，今後も大きく変化すると考えられる．今後も最新の研究動向や治療成績に注目していく必要がある．

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域連携クリティカルパスと疾病ケアマネジメント

日本疾病管理研究会 監修
武藤正樹・田城孝雄・森山美知子・池田俊也 編集

疾病ごとにケアマネジメントを行う最も有効なツール，地域連携クリティカルパス！
その意義と導入の方法に加え，がん，循環器疾患，脳卒中，糖尿病，大腿骨頸部骨折の事例を掲載！

中央法

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Original Article

Present situation of pTNM classification in Japan: Questionnaire survey of the pathologists of *Gan-shinryo-renkei-kyoten Byoin* (local core cancer hospitals) on pTNM classification

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pTNM classification is the most important element of surgical pathology. Internationally, the International Union against Cancer (UICC)-TNM is the standard TNM classification. In the present study questionnaires about the pTNM were sent to the pathology divisions of 288 institutions designated as *Gan-shinryo-renkei-kyoten Byoin* (local core cancer hospitals) on the basis of the *Cancer Control Act*. The questionnaire consisted mainly of questions about the TNM. There were 78 respondents, including 70 qualified pathology specialists, with a mean of 18.4 years of experience. The recognition rate of the important basic rules of the UICC-TNM were as follows: 'When in doubt, select the lower': 63.6% (49/77); 'Direct invasion to a lymph node is an N component': 61.0% (47/77); 'Only the extension of an invasive cancer is a T component': 45.5% (35/77). Few respondents knew the UICC criteria for judging whether multiple pulmonary lesions represent metastatic or multiple primary lesions. Only 26 (36.4%) of 77 pathologists were informed about cTNM routinely, suggesting that neither pathologists nor clinicians possess adequate knowledge about pTNM classification in many institutions. It is recommended that pathologists be informed about the rules and importance of pTNM through education, the revised Japanese classification of cancers, and self-assessment of their own institutes.

Key words: lung cancer, pTNM, stage, International Union against Cancer, uterine cervical cancer

The International Union against Cancer (UICC)-TNM classification (UICC-TNM) was developed by the UICC in cooperation with the American Joint Committee on Cancer (AJCC).[1–3] UICC-TNM is used internationally as the standard TNM classification. TNM and stage, a grouping of combined T, N and M according to vital risk, are essential for both research and intervention.[1,2] In Japan, cancer staging is reported on the basis of *Gan-toriatsukai-kiyakus* (Japanese classification of cancers: JC) for each tumor site in most institutes, which are also based on TNM system.

To be designated as *Gan-shinryo-renkei-kyoten Byoin* in Japan (local core cancer hospitals: LCCH), the *Cancer Control Act* requires LCCHs to perform hospital cancer registration. The registration is conducted using the UICC-TNM classification system.

In Japan little attention has been paid to the pTNM, although it is the most important component of surgical pathology. The handling of surgical specimens and the reporting of pathology findings are conducted in compliance with the JC at most institutes in Japan. JC is very useful for standardizing pathology reports, particularly for cancers of the stomach and large intestine.[4] Each JC is independent, however, and therefore the stage classification is conducted according to separate individual criteria. The absence of common rules may allow a pathologist to apply the criteria for the organ that they diagnose daily to other organs; for example, applying the criteria for a gastric cancer to a uterine cervical cancer. JC rarely have written criteria about points that are difficult to judge. JC have no help desk to respond to users' questions. In addition, JC cannot be used for international research or reporting because it consists of domestic rules. The UICC-TNM represents the international system. It has general rules and additional rules. The same rules are fundamentally used for all organs.[5] The UICC-TNM has a supplement book and a frequently asked questions (FAQ) section, and detailed rules are established according to various situations.[3] When stagers have further questions, the help desk can be contacted on the Web.[6] The same

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definitions used for the UICC-TNM have now been adopted for the TNM classification in various JC, for example thyroid cancer, the cancer of the head and neck, renal cancer, lung cancer, ovarian cancer and so on.

In the present study we administered a questionnaire survey (including quizzes) on pTNM classification to the pathologists of LCCH. The questions pertained to knowledge of the TNM classification itself and to the TNM staging of lung cancer. Although the survey was conducted only in Japan, it may be interesting for pathologists and other medical professionals abroad, because there have been no prior reports of questionnaire surveys of pathologists from cancer hospitals on the pTNM classification.

MATERIALS AND METHODS

Questionnaires on pTNM were sent to 288 LCCH in Japan that had been approved by 2007. The version that was translated into English and the summaries of the answers are shown in Tables 1–7. In the original Japanese version the inquiries did not have any number, but sequential numbers were then assigned for the purpose of the report. The major questions were about lung cancer because (i) the texts on TNM of the Japanese *Classification of Lung Cancer* by the Japan Lung Cancer Society (JCLC) are almost the same as those of the UICC-TNM;[7] (ii) the pTNM classification is complex;[1,2] (iii) lung cancer is an important cancer, because it is the leading and second leading cause of mortality in male and female subjects, respectively, in Japan;[10] and (iv) we assessed the pitfalls of the lung cancer pTNM classification in our previous study (N. Teramoto, R. Nishimura, H. Takahata, S. Sawada, T. Shinkai, unpubl. data, 2007).

RESULTS

We obtained 78 responses from 70 institutes by fax or mail. Each response was independent. The data from the authors' hospital (Shikoku Cancer Center) were not included. One response was not included in the total because it was a completely blank paper. In one response there were no answers to the questions pertaining to lung cancer because the response was from a pathologist of an institution that did not treat lung cancer patients. For 78 responses, the standard error at a risk rate of 0.05 is ±6.7% with a response rate of 10%/90%, ±8.9% with 20%/80%, and ±11.0% with 50%. For example, if 20% of 78 respondents selected answer A, it is estimated that 11.1–28.9% of the pathologists in Japan would select answer A at a risk rate of 0.05. Tables 1,2 list the questions and answers about the respondents themselves and institutions. Table 3 lists the questions and answers about the present situation of surgical pathology diagnoses at their institutions. Tables 4–7 outline the quizzes about and answers to the TNM classification. The correct answers to these quizzes are shown in bold underlined letters. The mean number of correct answers by correspondents to 19 of 20 questions was 9.4 ± 3.6 (1–17), excluding V-1, which was a subjective question.

Table 1 Section I: Inquiry about the respondents themselves

	Total
1. How many years have passed since you became a pathologist? Average: 18.4 years (0–40 years)	78
2. Are you a certified pathologist? Yes: 70 No: 8	78
3. What is your position at your institute? Full-time pathologist : 73, Part-time pathologist: 5	78
4. How do you rate your level of knowledge about lung cancer? Specialist: 2; Familiar: 4; average: 53; Little experience: 19	78
5. Do you think that you received enough education about TNM during your residency as a pathologist? Yes: 1 No: 70 No opinion: 7	78
6. Do you think you have attended a sufficient number of courses at academic conferences or workshops to learn about TNM? Yes: 1 No: 75 No opinion: 2	78

Table 2 Section II: About the respondents' institutions

	Total
1. How many beds are at your institute? average: 612 beds, (300–1200)	77
2. How many pathologists are working at your institute? average: 2.89 (1–16) 1 pathologist/institute: 16 2 pathologists/institute: 21	77
3. How many operated lung cancer specimens do you examine per year? Average: 63.4 (0–200)	75
4. How many operated uterine cervical cancer specimens do you examine per year? Average: 29.8 (0–130)	74

Respondents and institutions

There were 78 respondents with a mean length of experience of 18.4 years (Tables 1,2). Most of the 73 respondents were full-time specialists in pathology. Only one pathologist indicated that he had received satisfactory education about pTNM during his training to become a pathologist. Another indicated that he had received it at academic meetings.

Present status of surgical pathology diagnosis

Although pTNM is defined as a modification of cTNM on the basis of pathological findings, only 26 respondents (33.8%)

Table 3 Section III: Present status of pathological diagnosis of surgical specimens

		Total (*n*)
1. Do clinicians inform about cTNM on most cases?		
Yes: 26; No: 34; IDK: 17		77
2. Who classifies the T of pTNM of lung cancer?		
Pathologist: 55; Clinician: 20, Tumor registrar: 0; IDK: 2		77
3. Who classifies the M of pTNM of lung cancer?		
Pathologist: 9; Pathologist if possible: 29; Clinician in most cases: 29; Tumor registrar: 2; IDK: 7		77
4. Do you separately indicate the UICC-pTNM and JCLC-pTNM?		
UICC-TNM and JCLC separately	9	77
Only JCLC-TNM	38	
Only UICC-TNM	2	
Neither	17	
5. Who sections the surgical specimens?		
Pathologist: 67; Pathologist with surgeon: 4; Surgeon: 4; Laboratory technician: 2		76
6. Can you refer to the results of intraoperative lavage cytology while making a pathological diagnosis?		
Yes: 69 No: 7		76
7. Is the size of the lung cancer measured?		
Yes: 72 No: 5		77
7a. In the case of 'Yes', who determines the size?		
Pathologist: 62; Surgeon: 5; Pathologist with surgeon: 4; Laboratory technician: 1		72
7b. If the answer is 'No,' what is done instead?		
Transcription of the clinical size: 1; Size is not recorded in the report: 4		5
8. When is the tumor size measured?		
Size is measured on the gross examination of surgical specimens	43	77
Size is determined by mapping in the cut-out figure.	12	
Determination in HE specimens	9	
Not measured	5	
Others	7	
9. Do you routinely prepare tissue sections for screening of metastases to the peribronchial lymph nodes in the hilar region, in addition to preparing sections of the lymph node specimens collected separately?		
Yes: 49 No: 28		77
10. When pleural invasion is suspected, is the site of maximal invasion always excised?		
Yes: 76 No: 1		77
11. How is intrapulmonary metastasis from primary cancer of the lung differentiated from multiple primary lesions?		
Differentiated according to the UICC-AJCC criteria	8	76
Differentiated on an individual basis, but I know the UICC-AJCC criteria.	4	
Differentiated on an individual basis. I do not know the UICC-AJCC criteria.	42	
Not differentiated	15	
Others	7	

AJCC, American Joint Committee on Cancer; IDK, I do not know (includes no answer); JCLC, Japanese Classification of Lung Cancer; UICC, International Union against Cancer.

Table 4 Section IV: Quizzes concerning general knowledge of UICC-TNM

	% of correct answers	*n*	Ref
1. When in doubt between T1 and T2, T2 is chosen from the point view of benefit of the patient.			
Yes: 11, **No: 49**, IDK: 17	63.6	77	5
2. Direct invasion of cancer to the lymph nodes is regarded as an N component.			
Yes: 47, No: 17, IDK: 13	61.0	77	1,5
3. When cancer cell spillage into the body cavity occurs during the surgical procedure, the case is regarded as M1.			
Yes: 0, **No: 54**, IDK: 23	70.1	77	1,5
4. In patients in whom preoperative chemotherapy was efficient, pT is judged from the spread of the cicatricial tissue.			
Yes: 10, **No: 42**, IDK: 25	54.5	77	1,5
5. All primary malignant tumors (excluding hematopoietic neoplasms) of the tumor sites that have UICC-TNM classification can be classified according to TNM classification.			
Yes: 33, **No: 20**, IDK: 24	26.0	77	1,2,5

Bold underlined, correct answers. Ref: reference providing evidence for the correct answer.
IDK, I do not know; 'no response' was totalized as IDK; UICC, International Union against Cancer.

Table 5 Section Va: Quizzes concerning UICC-TNM of lung cancer

		% of correct answers	*n*	Ref
1. It is stated in the JCLC that TNM is the same as UICC-TNM for lung cancer. Yes: 14 No: 17 IDK: 46		—	77	1,2,7
2. It is stated in the AJCC staging manual that AJCC-TNM is the same as UICC-TNM for lung cancer. **Yes: 13**, No: 3, IDK:61		16.9	77	1
3. TNM in the Japanese Classification of Lung Cancer is the same as UICC-TNM. Yes: 27, **No: 17**, IDK: 33		22.1	77	1,3,7
4. Bronchioloalveolar carcinoma (BAC) is now defined as a non-invasive tumor according to the WHO tumor classification. Thus, how is pT of BAC classified?				
pTis	18	53.9	76	6,8
pT1	8			
The maximum diameter of the BAC is measured, and pT is decided from the size (diameter).	41			
Others	9			
5. The UICC-TNM supplement says that 'When size is the criterion for the cT/pT category, the size is the measurement of invasive component.' Then, how is pT decided in the case of infiltrating cancer with BAC (e.g. in the case of mixed BAC and papillary adenocarcinoma)?				
pT1	2	59.2	76	6,8
Only the size of the infiltrating cancer excluding BAC is measured to determine the T.	22			
The size including the BAC is measured to determine the pT.	45			
Others	7			
6. Pleural invasion is a T component. What are the criteria for T2 among the following?				
Extension to a site near the visceral pleura	1	43.7	77	9
Invasion of the elastic lamina of the visceral pleura.	31			
Exposure of tumor cells to the visceral pleural surface	37			
Invasion of the parietal pleura	2			
Others	6			
7. Microscopic examination of the lung cancer specimens revealed small cancer nodules at a site distant from the main tumor, which were not detected macroscopically. Both cancer nodules were pure papillary adenocarcinomas, composed of invasive cancer alone.				
Regarded as intrapulmonary metastasis	35	11.7	77	1
Not regarded as intrapulmonary metastasis	9			
Cannot say for certain without actual observation of the specimens under a microscope	29			
Others	4			

Bold underlined, correct answers. Ref: reference providing evidence for the correct answer.
IDK, I do not know. 'No response' was in totalized as IDK in 1–3 and omitted in 4–7.
AJCC, American Joint Committee on Cancer; IDK, I do not know (includes no answer); JCLC, Japanese Classification of Lung Cancer; UICC, International Union against Cancer; WHO, World Health Organization.

answered that they were informed about the cTNM by clinicians in most cases (Table 3). There were 20 respondents who indicated that they did not judge the pT by themselves (III-2). There were 71 respondents (93.4%) who indicated that they performed sectioning of surgical specimens by themselves (III-5). Fifteen respondents, however, indicated that the lung tumor size for determining T was not determined by pathologists, including five respondents who indicated that the size was not measured on pathological specimens (III-7). Twenty-eight respondents (36.4%) indicated that they do not prepare specimens of peribronchial lymph nodes from the hilar region, which are the first targets of lymph node metastasis of lung cancer (III-9).

Answer validation of the quizzes

Section IV: Quizzes concerning general knowledge of UICC-TNM

Section IV includes questions on general knowledge of the UICC-TNM (Table 4). When there is a doubt, the tumor must be classified into the lower category according to the UICC-TNM general rule No.4 (IV-1).[5] It is also an important rule of the UICC-TNM that direct invasion to lymph nodes is regarded as the N component (IV-2).[5] Neither of the two rules is specified in any of the JC. The correct answer rates were 63.6% and 61.0%, respectively, but considering that these questions had two choices, the number of pathologists who had sufficient knowledge for the rules will be much smaller. ypT is judged from the actual existing tumor, not from the cancer scar (IV-3).[1,5] Tumor spillage during surgery has no influence on the TNM of tumors except for ovarian tumors (IV-4).[1,5] Carcinoid, sarcoma and melanoma, as well as hematopoietic tumors, are excluded from the TNM classification in most tumor sites (IV-5) because they do not have a similar prognosis as the carcinomas of the same TNM.[1,2]

Section Va: Quizzes concerning UICC-TNM of lung cancer

Section Va includes questions about the TNM classification of lung cancer (Table 5). In the JCLC it is implied but not written clearly that the JCLC-TNM and UICC-TNM are the same.[7] We do not know the correct answer to V-1, but JCLC-

Table 6 Section Vb: Quizzes concerning intrapulmonary metastasis and size of lung cancer

	% of correct answers	*n*	Ref
Questions 8–12. Choose the case in general terms. A clue: Questions 8, 9 and 12 refer to the presence of cancer nodules in the same lobe, and questions 10 and 11 refer to the presence of cancer nodules in different lobes.			
8. Two tumor lesions not adjacent to each other were visualized at the time of preoperative CT. Examination of tissue specimens from both tumors revealed the same histological type of adenocarcinoma. The smaller node does not have BAC around it. If the smaller lesion is regarded as intrapulmonary metastasis, the case would be evaluated as pT4pN0cM0 and stage IIIB. If it is not regarded as intrapulmonary metastasis, the case would be evaluated as pT1pN0cM0 and stage IA. Which of the evaluations is valid?			
Regarded as intrapulmonary metastasis: 61			
Not regarded as intrapulmonary metastasis: 10	13.2	76	1,6
Others: 5			
9. Under the same conditions as those in Question 8, metastasis was detected in the #12 lymph node alone. If the smaller lesion is regarded as intrapulmonary metastasis, pT4pN1cM0 and stage IIIB. If it is not regarded as intrapulmonary metastasis, pT1pN1cM0 and stage IIA.			
Regarded as intrapulmonary metastasis: 59			
Not regarded as intrapulmonary metastasis: 8	78.7	75	1,6
Others: 8			
10. Under the same conditions as those in Question 8, metastases were detected in the #12 lymph node alone. If the smaller lesion is regarded as an intrapulmonary metastasis, pT1pN1pM1 (PUL) and stage IV. If it is not regarded as an intrapulmonary metastasis, pT1pN1cM0 and stage IIA.			
Regarded as intrapulmonary metastasis: 49			
Not regarded as intrapulmonary metastasis: 16	21.1	76	1,6
Others: 11			
11. Under the same conditions as those in Question 8, metastases were detected in #7 lymph node alone. If the smaller lesion is regarded as an intrapulmonary metastasis, pT1pN2pM1 (PUL) and stage IV. If it is not regarded as an intrapulmonary metastasis, pT1pN2cM0 and stage IIIA.			
Regarded as intrapulmonary metastasis: 54			
Not regarded as intrapulmonary metastasis: 11	71.1	76	1,6
Others: 11			
12. Under the same conditions as those in Question 8, metastasis was detected in the liver. If the smaller lesion is regarded as an intrapulmonary metastasis, pT4pN0cM1 (HEP) and stage IV. If it is not regarded as an intrapulmonary metastasis, pT1pN0cM1 and stage IV.			
Regarded as intrapulmonary metastasis: 61			
Not regarded as intrapulmonary metastasis: 8	80.3	76	1,6
Others: 7			
13. The size measured by CT was 3.2 cm, while the size after fixation at the time of resection was 2.8 cm. The lesion is evaluated as cT2, but pT is evaluated as pT1.			
Yes: 56, No: 11 IDK: 10	72.7	77	5
14. The size measured after fixation was 3.2 cm, while the size in the HE specimen was 2.8 cm.			
Yes: 12 **No:54** IDK: 11	70.1	77	5

Bold underlined, correct answers. Ref: reference providing evidence for the correct answer.
BAC, Bronchioloalveolar carcinoma; IDK, I do not know; 'no response' was totalized as IDK.

Table 7 Section VI: Quiz concerning extension of intra-epithelial component

	Answer
1 The extension of cervical cancer to the portio supravaginalis is a factor for classification as T2a in cases of cervical squamous cell carcinoma;	
a In the presence of histological evidence of carcinoma *in situ*, the lesion is evaluated as pT2a, if vaginal extension is suspected macroscopically.	5
b In the presence of histological evidence of carcinoma *in situ*, the lesion is evaluated as pT2a, even if vaginal extension is not suspected macroscopically.	32
c **When evidence of invasive squamous cell carcinoma of the vagina is present histologically, it is evaluated as pT2a, even if vaginal involvement is not suspected macroscopically.**	35
d When vaginal involvement is suspected macroscopically, the lesion is evaluated as pT2a, even if evidence of carcinoma in situ is absent histologically.	0
e When vaginal involvement is suspected macroscopically, the lesion is evaluated as pT2a, even if evidence of infiltration is absent histologically.	0
No answer	5

The correct answer is c. The percentage of correct answers was 45.5%. Four respondents marked letters a–c together. They were dealt with as 'b' because b includes all the conditions.

TNM is distinctly different from UICC-TNM on minor rules (V-3).[1–3] For example, see the answer for V-6 in the next paragraph. AJCC-TNM and UICC-TNM of lung cancer are identical (V-2). UICC and AJCC worked together to make the same TNM system for all organs in the sixth edition,[1] although there are small numbers of minor differences.

It is plausible to evaluate bronchioloalveolar carcinoma (BAC) as pTis, because it is now defined as a non-invasive carcinoma.[11,12] It is also plausible to measure the size from the invasive component alone according to the principles of UICC-TNM.[5] At the moment, however, BAC is exceptionally regarded as an invasive cancer in UICC-TNM (V-4, -5).[6,8] The T2 criterion of JCLC-TNM requires complete exposure of the tumor cells to the visceral pleural surface,[7] while that of UICC-TNM includes the invasion of the elastic lamina (V-6).[9] The frequency with which JCLC-T1 is UICC-T2 depends on the patients who undergo surgery at each institution. At Shikoku Cancer Center, for example, JCLC-T1 is UICC-T2 according to the criterion in approximately 5% of patients (N. Teramoto, R. Nishimura, H. Takahata, S. Sawada, T. Shinkai, unpubl. data, 2007). Microscopic nodules that cannot be confirmed macroscopically or radiologically, are not evaluated as intrapulmonary metastases (V-7).[1,5] The correct response rate was only 11.7%. The criteria of intrapulmonary metastasis are summarized in Table 8.

Section Vb: Quizzes concerning intrapulmonary metastasis and size of lung cancer

Questions V-8–12 include questions about the differentiation of intrapulmonary metastasis from multiple primaries (Table 6). These questions were offered with the sentences 'You may think that you cannot choose a correct answer without checking the actual specimens. But please select an answer that fits best to the rules in general terms'. The UICC-TNM FAQ section says 'A 2-cm primary adenocarcinoma with multiple deposits of adenocarcinoma in another lobe, negative lymph nodes and no other metastasis is M1' (Table 8).[9] But this is a cancer showing multiple deposits. According to the AJCC staging manual, a subject with 2 nodules can be regarded as having intrapulmonary metastasis if at least one of the following three criteria is met: (i) lymph node metastasis of the common lymphatic drainage; (ii) mediastinal metastasis; or (iii) extrathoracic metastasis (Table 8).[1] Therefore, case V-8 with N0M0 is not regarded as intrapulmonary metastasis (pT1N0M0).

Intrapulmonary metastasis within a lobe is T4, while that in different lobes is M1(PUL). Because case V-9 is T4N1M0 or T1N1M0, it is certain that two nodules were in the same lobe. Therefore, the metastasis to lymph node 12 (lobar nodes bronchi) is in a common lymphatic drainage. Case V-9 can be regarded as intralobular pulmonary metastasis (pT4N1M0) according to criterion A. In contrast, case V-10, pT1N1M1(PUL) or pT1N1M0 is a multiple primary case because the case involved two nodules in different lobes and lymph node 12 is not in common lymphatic drainage. None of the A-C criteria are met in case V-10 (pT1N1M0). Case V-11 with N2 (mediastinal metastasis) can be regarded as intrapulmonary metastasis even if the node is present in different lobes (criteria A and B; pT1N2M1). Case V-12 with distant metastasis is M1(PUL) due to criterion C (pTN0M1). The correct answer rates for V-8 and V-10 (right answer: 'Not regarded as intrapulmonary metastasis') were very low (Table 6). The right answer rates for V-9, -11, and -12 (correct answer: Regarded as intrapulmonary metastasis) were high, probably because 44 (57.9%) of the 76 respondents answered all the cases as intrapulmonary metastasis.

When pT is determined by tumor size, the size of unfixed material is used first, the size of a fixed tumor as next best if measurement of unfixed material is impossible, and the size on preparatory slides is used as a last resort (V-13, -14).[5,6] The size measured on CT is not used as the pathology size if the actual size of a pathology specimen can be measured.

Section VI: Quiz concerning extension of intra-epithelial component

This question was submitted as a quiz concerning uterine cervical cancer to conceal the fact that this question was actually about the extension of an intra-epithelial component. In general, the extension of an intra-epithelial component does not change the T (VI-1).[5,6] The correct answer to this question was given by 35 (45.5%) of the 77 respondents (Table 7).

Table 8 Criteria of intrapulmonary metastasis

Description	Ref
Microscopic nodules that are not found radiologically or macroscopically are not regarded as intrapulmonary metastasis.†	1,5
A primary adenocarcinoma with *multiple deposits* of adenocarcinoma in another lobe, with/without lymph nodal and/or distal metastasis is M1.‡	9
Two separate nodules are not likely to be metastatic without any of the following‡ A Lymph node metastasis of the common lymphatic drainage B Mediastinal metastasis C Extrathoracic metastasis.	1,6

†This rule is written in the AJCC staging handbook, Part IV. It is based on UICC-general rule No. 5.

‡Note that the rule for multiple deposits and that for two (or a few) nodules are different. The former will also be true for carcinomas other than adenocarcinoma. The latter is described only in the AJCC staging handbook but is also valid on UICC-TNM.[6]

AJCC, American Joint Committee on Cancer; IDK, I do not know (includes no answer); JCLC, Japanese Classification of Lung Cancer; UICC, International Union against Cancer.

DISCUSSION

Questionnaires were sent to the pathologists working in LCCH. When considering the mean number of beds (approx. 600) and the mean number of pathologists (approx. three; Table 2), and that these pathologists belonged to LCCH, the responders handle many cancer cases routinely. Because there were only 78 respondents, there was a standard error of approximately 10%, but the purpose of the questionnaire survey was not to precisely estimate the correct answer rate from the population. We consider the results of this questionnaire survey sufficient to represent Japanese pathologists' knowledge about pTNM. As shown by this questionnaire survey, there is insufficient knowledge about the UICC-TNM among pathologists in Japan, but we expected these results.

It is noteworthy that the percentage of correct answers to questions concerning the following important criteria was only approximately 60%, despite the fact that the question presented two choices: for example, 'When it is difficult to judge TNM, the lesion is classified into the lower category' (IV-1), 'direct invasion of the lymph node is an N component' (IV-2) and so on (Table 4). It was even less recognized that the extension of a non-invasive component of a carcinoma does not raise T (Table 7).

Because pTNM classification is assigned by modification of cTNM based on the pathological findings,[3] pTNM classification without information on the cTNM makes little sense. In >60% of the institutions, however, the pathology division was not informed on the cTNM by the clinical divisions, suggesting that not only pathologists, but also the majority of clinicians give little importance to evaluating the pTNM of the pathological specimens (Table 3). Judging whether multiple pulmonary lesions are multiple primary tumors or multiple metastases changes the stage of a lung cancer considerably. According to III-11, the differential diagnosis between intrapulmonary metastatic tumors versus multiple primary tumors is not based on the UICC-AJCC criteria or on any other common criteria, but rather on individual judgment in most institutes (Table 3). The results of judgment based on the UICC-AJCC criteria are not always the most appropriate in actual clinical cases. It is not justified, however, for each pathologist to decide pTNM on their own individual criteria, without knowing the common criteria. Because staging is based on the surveys of TNM and prognosis at many institutions, it is not possible to stage a case without using common criteria shared among institutions.[1,2] Accumulating information on cancers precisely staged on common criteria is essential to improving the reliability of the TNM system in the future.

When a pathologist explains the pathological findings of a cancer to a patient directly in the pathologist's office, pTNM assumes great importance, because it is the most important prognostic predictor. The prognosis is the major concern of patients. Appropriate sectioning of a surgical specimen is impossible without comprehension of the pTNM classification. Wrong pTNM will lead to deviations of cTNM. It goes without saying that pTNM classification must be determined by the pathologists who make the pathological diagnosis, not by clinicians or tumor registrars who do not actually examine the specimens.

The results of the questionnaire survey indicated the faults of the surgical pathology system in Japan. For the establishment of evidence-based medicine, pTNM must be standardized. TNM classification itself is not difficult (according to our experience from unpublished data). The certification test for a pathology specialist in Japan should include questions to test knowledge of TNM. Because most responders answered that they had not been educated about TNM at all, education through training sessions at conferences might also be useful. Most JC cite the texts of UICC-TNM of the organs, but the basic rules of UICC-TNM, which TNM stagers should know before use, are not described. The JC needs to include information explaining the importance of staging, a detailed explanation of the UICC-TNM, and a list of reference books.

In addition to questionnaire surveys, investigating the accuracy of actual recorded pTNM is necessary to determine whether the pTNM is being correctly used. The present survey was performed in Japan. It is not certain how much pathologists in other countries know about the rules of pTNM. It is recommended that the accuracy of pTNM be investigated to assure the quality assurance of pathological diagnoses.

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特集

未来をきり拓く在宅緩和ケア

緩和ケア病棟における地域との連携

Palliative Care Units Affiliated with Community Medical Services

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Key words：緩和ケア病棟，在宅緩和ケア，連携

●緩和ケア 19：419-422, 2009●

はじめに

わが国における緩和ケアは，おもに緩和ケア病棟の増加というかたちで発展してきた．しかし近年は，家に帰りたいと望む患者の思いを尊重した在宅緩和ケアが重視され，緩和ケアを受けられる場所は多様化している．また，緩和ケアの概念から「終末期」が外され，緩和ケア病棟のあり方にも変化が求められている．

本稿では，在宅緩和ケアを主軸とした，これからの緩和ケア病棟のあり方と地域との連携について考察する．

制度改正にみる緩和ケア病棟の位置づけ

2007年4月施行の「がん対策基本法」に基づいて，がん対策推進基本計画が策定された．その中に「治療の初期段階からの緩和ケアの実施」が盛り込まれた[1]．また2008年診療報酬改訂では，緩和ケア病棟入院料の留意事項として以下が記載された．

・緩和ケア病棟の退院日に，退院後に使用するものとされた薬剤料は別に算定できる．

・悪性腫瘍患者のケアに関しては，『Evidence-Based Medicineに則ったがん疼痛治療ガイドライン』（日本緩和医療学会），『がん緩和ケアに関するマニュアル』（厚生労働省・日本医師会監修）などの緩和ケアに関するガイドラインを参考とする．

・地域の在宅医療を担う医療機関と連携し，緊急時に在宅患者が入院可能な体制を確保している．

・連携医療機関の患者に関し，緊急相談などに対応できるよう，24時間連絡体制を確保している．

・連携医療機関の医師・看護師・薬剤師に対して，実習を伴う専門的な緩和ケアの研修を行っている．

同じ視点から下記の診療報酬改定も行われた．

1）がん性疼痛緩和管理指導料において，算

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定には外来，入院，在宅を問われない．

2）介護老人保健施設，療養病床における医療用麻薬の算定が包括外となった．

3）緩和ケア診療加算条件に外来診療が容認された．

上記により，緩和ケアの場所は制度上入院から在宅まで大きく広がった．

当院在宅緩和ケア支援と緩和ケア病棟

四国がんセンター（以下，当院）は病床数405，医師数80名，平均在院日数17日，病床利用率91％（2009年6月）のがん専門急性期病院である．

2003年4月から緩和ケアチーム活動が始動し，その活動の一環として退院支援，在宅支援が開始された[2]．2006年4月の新築移転に伴い緩和ケア病棟が開設され，同時に退院調整・在宅支援を担う部門としてがん相談支援・情報センター（以下，相談支援センター）が開設された．

1 当院の退院調整・在宅支援の体制

がん診療連携拠点病院には，「がん相談支援センター」の設置が義務づけられている[3]．

当院の支援センターは患者支援のための院内各部門との調整，外部医療機関との調整の中心として位置づけられている[4]．相談支援センターは6名でスタートし，現在は11名（看護師4，ソーシャルワーカー1，遺伝相談員1，臨床心理士1，事務員3，研究補助員1）で構成されている．相談支援センターでは医療連携機能と1つとして「退院調整連携パス」を導入している[5,6]．

これは，(1) 入院時から退院後の療養のスクリーニングを開始し，(2) 入院治療中に同時並行で病棟スタッフによる在宅療養準備を促し，(3) 遅滞なく外部医療機関，訪問看護ステーションなどとの連携を調整する，ツールである．緩和ケア病棟入院患者には全例相談支援センターが関わり，退院後の在宅サポートも緩和ケア外来と共同する．

2 当院の緩和ケア病棟[7]

当院の緩和ケア病棟（25床全室個室，医師専任1名，併任1名，後期研修医1名，看護師20名）の運営の理念は「私たちはがんとともに生きる人々の尊厳を大切にし，・がんに伴う身体的，精神的症状の緩和に努めます．・患者様とそのご家族の地域での生活を重視した療養を支援します．・地域における緩和医療の普及と向上に貢献します」である．緩和ケア病棟の役割は，「1．専門的緩和ケアの導入と適応，2．在宅移行までのワンクッション，3．在宅患者のバックアップベッド」と位置づけており，在宅緩和ケアの最後の砦として機能する．

緩和ケア病棟が「生活の場の提供ではない」ことは強調されておくべきである．長期の療養が必要とされる場合は終末期の療養生活を設計する．そのために心がけている点は，次の2点である．

1．緩和ケア移行時には患者家族と話し合い，緩和ケア病棟入院の目的を明確にする．すなわち，入院時に退院の目標を立てる．

2．逆に在宅療養中に入院対応が必要な場合は，緩和ケア病棟としていつでも即入院を受け入れる．

緊急時の受け入れを保障することは必須である．2009年6月現在，緩和ケア病棟登録患者120名余りが在宅療養中であり，かかりつけ医，訪問看護ステーションと連携しているのは3割である．通院不能のため，もっぱらかかりつけ医が在宅診療し，入院時のみ対応する患者は1割である（前記3割の3分の1）．

患者・家族に心配，不安がある時はまず第1に在宅医，訪問看護ステーションへの相談を指導しているが，同時に緩和ケア外来・相談支援センターへいつでも連絡がとれることも案内している．しかし，緩和ケア病棟への入院が必要な場合はほぼ予定入院となっており，夜間の緊急対応は多くない（多い時で月4，5名程度）．医療者間での日常の密な情報交換が重要である．

緩和ケア病棟の円滑な運営のためには，緩和ケア病棟の受け入れ基準と，在宅緩和ケアの早期準備が重要である．

表1　緩和ケア病棟，相談支援センター開設後

・2007年度緩和ケア対応患者数	408
・死亡患者（2008年4月10日調査時点）	282
・緩和ケア病棟で死亡	204
・院内一般病棟で死亡	20
・他病院で死亡	23
・自宅で死亡（死亡の12％）	35
・外来・在宅フォロー中	63
・疼痛/症状コントロール対応	63

1．緩和ケア病棟の受け入れ基準の明確化

在宅緩和ケアのバックアップベッドとして機能するためには，緩和ケア病棟の受け入れ基準を明確にしておくことが必要である．

（a）がん患者である．
（b）患者が病名，病状を理解している．
（c）治癒が望めなくなった患者である．
（d）治癒を目的とした積極的治療を望まない患者である．
（e）症状が著しく，入院により緩和ケアを必要とする．
（f）患者が入棟を希望し，家族の同意が得られている．
（g）緩和ケア病棟の説明を受け，緩和ケアの主旨を理解している．
（h）緩和ケア病棟登録患者の介護者が休養を必要とする．
（i）主治医からの診療情報が得られている．

上記の観点を判定会議でチェックし，総合的に判断する．入院のタイミングは病棟師長と緩和ケア医が相談する．

2．在宅緩和ケアへの早期対応

緩和ケア病棟入院受け入れ時に在宅緩和ケアにおける問題をスクリーニングする[8,9]．すなわち，在宅療養における留意点，介護・家族支援の体制とその準備状況などを入棟判定会議で確認する[5,6]．

緩和ケア病棟の運営状況を表1，2に示した．在院日数は中央値13日と短く，多くの患者は終末期近くまで在宅で緩和ケアを受けている．緩和ケア病棟が関わった患者の在宅看取り率12％がわれわれの地域の総合的な実力である．現実はまだ厳しい．なお，当院は在宅診療・訪問看護の部門を持たないため，在宅看取りはすべて在宅医との連携による．

表2　当院緩和ケア病棟の運営状況

	2006年度	2007年度	2008年度
死亡退院数	179	212	258
在宅へ	48	44	63
転院	7	5	7
転棟	6	1	5
入院中	0	0	5*
入退院総数	240	262	338
入院日数（中央値）	18日	13日	13日
（平均在院日数）	—	24.2日	19.1日

*2009年4月末現在

緩和ケア患者の地域連携

われわれの経験に基づき，緩和ケア患者の地域連携を進めるために必要な観点をまとめた．

1 在宅医・かかりつけ医との連携

相手の対応力に応じて臨機応変に連携を組む姿勢が肝要である．かかりつけ医が平日の外来診療しか対応できなくても，患者との信頼関係があれば連携は成立する．完璧な在宅緩和ケアより，常に緩和ケア連携ネットワークの拡大を意識しておくことが重要である．できる範囲をお願いし，残りはいかようにも緩和ケア医が補えばよい．予期せぬ，すばらしい在宅医に巡り会うことも多い．

2 病院主治医（治療医）との連携

病院主治医には，しばしば在宅緩和ケアの認識が抜けている．緩和ケア医がかかりつけ医・訪問看護ステーションを探し，緩和ケアの立場から診療情報提供書を書くなど，その時点で連携を組み立てる作業をいとわないことが必要である．

患者が「緩和ケア」を受け入れられない場合のおもな原因は，主治医からの説明不足である（患者の無理解ではない）．経験上，主治医の変革は容易には望めないため，われわれは「緩和ケア」の受け入れができていない患者についても（主治医継続を条件に）緩和ケア病棟に受け入れることとした（2008年9月から）．

その結果，判明したのは，緩和ケア病棟に転棟するタイミングで主治医の説明が劇的に変わったことである（主治医は自分の説明が足りていないことをそのタイミングで初めて自覚する）．病院主治医の意識改革，地域における緩和ケアレベルの向上は今後の緩和ケア研修会（PEACE

〈Palliative care Emphasis program on symptom management and Assessment for Continuous medical Education〉プロジェクト）に期待したい[10]．

3 地域の情報源の活用と地域差への対応

医療機関情報は医療機能情報公表制度（2007年）に基づき都道府県を通じて住民らに公表されている[11,12]．在宅緩和ケアの情報については十分とはいいがたいが，今後は「がん患者必携」で地域情報も整理される[13]．

愛媛県松山圏域（圏域人口65万人）には在宅医療専門の医療機関が現在4施設存在し，専門外に在宅診療を担う開業医療機関が多い[14]．松山市医師会は1997年から在宅3事業に関わっており，2000年頃からの在宅医療懇話会，在宅医の会などの勉強会活動も活発である．現在，松山圏域では，患者・家族が希望する在宅緩和ケアはほぼ実現できている．

しかし，松山圏域を離れると地域差が著しい．相談支援センターは実地の連携と経験に基づいた生の情報と調整のノウハウを蓄積し，個々の患者に活かす能力が求められている．地域の訪問看護ステーションを手がかりにするなど，人的ネットワークが有効である．

4 連携ツールの活用

緩和ケア患者の連携としてがん性疼痛コントロールの連携ツールを開発し，利用している[15]．現段階ではおもに経過記録表を用いるだけのことが多く，連携ツールとしての活用は十分ではない．ツールの改良と連携の基盤整備が必要である．

現在，5大がんの地域連携クリティカルパス開発の成果に期待したい．

おわりに

在宅緩和ケアの重要性が認識されるとともに，最近は急性期病院に併設された緩和ケア病棟の平均在院日数が急速に短縮してきている．特にがん診療連携拠点病院などに設置される緩和ケア病棟は地域，在宅で過ごす患者を支えてこそ，存在価値がある．

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実践報告

がん化学療法における患者支援ツールの開発

—経口抗がん剤の円滑な薬薬連携を目指して—

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Development of a Patient Supporting Tool in Cancer Chemotherapy

— To achieve a smooth collaboration between a hospital pharmacy and a community pharmacy in the oral anticancer drugs —

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要旨

今日のがん化学療法は入院治療から外来治療へ移行している。四国がんセンターでは、経口抗がん剤の院外処方について副作用のモニタリング機能を付加して、患者のセルフメディケーション及び生活の質（Quality of Life：QOL）の維持・向上を目的に患者日誌を試用した。また、本日誌は患者が保険調剤薬局へ持参することで当院との円滑な治療に関する情報共有を図ることも目的としているので、いわゆる院内外における治療の情報伝達を図るクリニカルパスであると言える。今回、日誌の作成に至るまでの経緯、問題点、試用した上での実践報告を行う。

キーワード
＊がん化学療法　＊クリニカルパス　＊経口抗がん剤　＊患者支援　＊薬薬連携

Key words
＊ cancer chemotherapy　＊ clinical pathway　＊ oral anticancer drug　＊ patient support
＊ collaboration between a hospital pharmacy and a community pharmacy