

provider facilities. Furthermore, the panelists proposed 17 and 22 new item candidates in the first-round ratings and further 10 and 5 during the face-to-face meetings for gastric and colorectal cancer, respectively. These were combined with each other into 17 and 12 new item candidates for the second-round rating. In addition, 23 and 22 items among the current checklists were modified before the second-round rating.

The panelists considered that the current checklists for screening provider facilities lacked the important domain of 'Tracking complete diagnostic evaluation results for screening positive persons', and one item, 'does the provider keep the results of complete diagnostic evaluation for 5 years?' was added to the list for both colorectal cancer and gastric cancer in this domain. For the colorectal cancer checklist, another item was added, 'Can the provider report the methods and results of complete diagnostic evaluation in response to a request from the prefectural and/or municipal government?'

In the second round, 74 and 68 items were rated for gastric cancer and colorectal cancer, respectively. Among these, four items in total, namely one item each for cancer and settings, were excluded because another item describing the same content differed only by the time required (e.g. keeping records for 5 versus 3 years) but had a better rating distribution. Six and two items were further dropped because of low median ratings or lack of agreement. The final set of checklist items consisted of 66 and 64 for gastric cancer and colorectal cancer, respectively.

Most items rated low had alternative items rated high for the same topic. For example, an item concerning the keeping of results of colorectal cancer screening tests for 3 years was rated low, because most panelists thought the duration should be 5 years, and thus rated the 5-year item highly. Of note, two items which indicate patient explanations, namely (i) possible complications of the barium imaging and (ii) possible complications and benefits of screening, were dropped because of a disagreement concerning the former and a low median rating of the latter.

DISCUSSION

In this study, we evaluated the current checklists for public screening programs and facilities for gastric and colorectal cancer, and developed a revised version to improve on them. The participation of panelists from various backgrounds enabled the checklists to be discussed from many perspectives. The panel found that the current checklists were generally appropriate, but suggested a number of revisions to improve their validity and clarity. The revised checklists and the comments made during the discussion provide important insights into the reality of Japanese cancer-screening systems.

Several important points were raised during this process. First, the panelists questioned whether the checklists should

apply to individualized screening services typically provided by local medical associations. Quality control among these individualized screening settings is relatively difficult because examinees visit the facility comingled with sick patients. Owing to the small scale of these settings, management of the services becomes relatively inefficient, making the time and resources spent on each examinee relatively greater than in large-scale screening settings. The lower follow-up rate for complete diagnostic evaluation after individualized than mass screening may indicate this difficulty (5,6). Although panelists first felt that it may not be fair to apply the same standards to these settings, they finally determined that, from the examinee's perspective, the level of quality control must be the same regardless of facility size. We therefore decided not to distinguish individualized from mass screening settings in examining the appropriateness of the checklists.

Second, some panelists pointed out that the boundary of responsibility between municipal government and service providers is in reality ambiguous. In particular, uncertainty exists on the breakdown of tasks during the transition from recruiting to providing services, such as explaining the risks and benefits of screening to examinees and reminding them that they should not skip follow-up diagnostic evaluation if their screening results are positive. Finally, the panel decided that the responsibility for these lies with both the municipal government and screening provider facilities: even though only one actually provides the explanation, the other is responsible for ensuring that this has been done, and for providing it if the other fails to do so.

Third, the panel realized that the guidelines to which the current checklists for colorectal cancer screening refer were no longer available in the market. However, since the recommendations of the guidelines were relatively simple and covered by other items in the checklists, the panel finally decided that they simply omit this item and leave the individual items in the list. In contrast, the gastric cancer checklists indicated that their imaging methods needs to be consistent with the methods recommended by the Japanese Society for Gastrointestinal Cancer Screening, and specified several parts such as the number of images and the concentration of barium. The panel considered that these individual items do not cover the whole complexity of the photofluorography method described in the guideline, nor represent the most important aspects of the methods, and therefore excluded these items.

Our study must be interpreted within several limitations. First, a prior study reported that the composition of a panel's members influences the distribution of its ratings and potentially its conclusion (17,18). This weakness is ameliorated if the size of the panel is increased such that it can capture all opinions in the field. Against this, broad coverage risks a decrease in the level of individual participation and depth of discussion. We consider that all panelists in our present study were fully committed and provided deep insights into the problems of frontline cancer screening settings.

Additionally, our panelists included only physicians and technicians. This may have led our results to reflect a highly technical view. Participation of members from other backgrounds such as facility administrators and government officials might have been desirable to achieve a more balanced view. Furthermore, our process provides only face validity from the multiple perspectives of the panelists using a formal process to examine the level of consensus. Future research needs to confirm that the satisfaction of the checklist relates to high-quality cancer screening in other measures, such as screening rates and complete diagnostic evaluation receipt rates, and to an eventual decrease in mortality rate among the residents. Nonetheless, previous research has confirmed that suitably conducted panel processes do produce quality indicators and appropriateness criteria which agree with the opinion of a community sample of practicing physicians (19); that meeting the criteria is associated with lower mortality (20); and that the results are reproducible with different panel members (21). Given that such validation studies require time and resources and the urgency of quality control task implementation, our present study results, which support the current checklists, should be used as a basis for the immediate implementation of quality control evaluation of cancer screening. The continuous improvement of both checklists as well as cancer screening is essential to the ultimate goal of reducing cancer mortality.

CONCLUSIONS

Development of pertinent tools is the first step in the quality control of cancer screening. Through a formal process of examination, we confirmed the appropriateness of the current checklist and proposed draft-revised checklists for gastric and colorectal cancer screening. The various backgrounds of panelists enabled us to examine the checklists from multiple perspectives. These checklists should be used to identify problems in improving systems aimed at high-quality cancer screening, and decreasing cancer mortality.

SUPPLEMENTARY MATERIAL

Supplementary Material is available at *Japanese Journal of Clinical Oncology* online.

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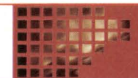
Conflict of interest statement

None declared.

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Opinion of Japanese rheumatology physicians on methods of assessing the quality of rheumatoid arthritis care

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Abstract

Objective To examine the opinion of rheumatology physicians in Japan regarding desirable quality assessment methods.

Methods We conducted a cross-sectional self-administered mail survey on a random sample of physicians and surgeons registered with the Japan Rheumatism Foundation. In the survey, respondents were asked to rank seven proposed assessment methods for the quality of rheumatoid arthritis care, namely patient satisfaction, risk-adjusted outcomes such as complication incidence and admission rate, guideline compliance, waiting time at clinics, voting by local general practitioners, degree of newspaper and magazine reportage, and volume of patients receiving treatment for rheumatoid arthritis.

Results Among 531 respondents (response rate 48%), the respondents ranked patient satisfaction most favourably (mean rank 1.6), followed by complication/admission rate and number of patients. Guideline adherence was ranked almost the same as voting by local physicians. Waiting time and media reportage were not considered good methods for quality evaluation. Ranking distribution did not differ by working facility or place, volume of patients or years in practice. Multivariate analysis revealed that respondents who care for a large number of rheumatoid arthritis patients (>40 regular patients) were less likely to rank guideline adherence highly (first to third) than those who care for few patients (≤ 10 regular patients), with an odds ratio of 0.38 ($P < 0.01$) after adjustment for other variables.

Conclusions A majority of Japanese rheumatology physicians consider patient satisfaction the most trustworthy method of assessing the quality of rheumatoid arthritis care. Future research should explore convincing methods of assessing the technical quality of rheumatoid arthritis care.

Introduction

The quality of medical care has gained increasing public attention. Many studies have reported unexplained variations in care across geography [1–4], setting [5] and race [6] in western countries, and gaps between current standards and actual practice [7,8]. This growing concern has fuelled activities to measure and publicly report the quality of medical care for accountability purposes [9,10], and many settings in western countries have gone so far as to adopt payment schemes that reward a high quality of care [11–13]. Concern is growing in Japan also, where professionals have traditionally enjoyed freedom from rigorous quality scrutiny, as exemplified by increases in the number of malpractice litigation cases [14] and in media reporting of quality information, such as the surgical mortality of hospitals based on their own surveys [15,16]. A clear need to systematically measure the quality of care has emerged.

One popular way of measuring quality is to evaluate the process of care in comparison with a set of explicit criteria [7,8,17]. These explicit criteria usually describe standards of care based on clinical evidence and professional consensus, and quality is calculated as the proportion of patients who receive the described care among those eligible for it. These criteria sometimes derive from clinical practice guidelines, which are usually based on clinical evidence and professional consensus. Although the quality of care can also be measured using structural (i.e. staff–patient ratio and presence/absence of high-tech equipment) or outcome (patient survival or re-admission rate) measures, process measures have advantages, such as not requiring the statistical case-mix adjustment necessary in outcome measures and the ability to examine the care provided, for which providers are directly responsible.

Despite the growth of quality measurement in western countries, provider opinions of how quality should be measured are

rarely examined. Providers naturally oppose the idea of 'being measured' and tend to be critical of quality measurement. Simple questioning on whether a certain quality measurement (e.g. process measurement) is appropriate may result in a majority negative response which merely reflects reluctance to be measured. In this regard, a survey of US generalist physicians revealed that 70% of respondents felt that quality is not adequately measured at present, while a majority of the same sample were willing to be paid on quality provided that quality is adequately measured [18]. A qualitative study and an anecdotal story show that the current quality measurement schemes can distort the traditional goodness of the physician-patient encounter [19]. If these critiques shed light on the problems of quality measurement, the need to assure the accountability of health care providers may warrant the consideration of alternative ways of measuring quality. An understanding of physician opinions of how quality should be operationally measured may help identify optimum approaches and facilitate physician cooperation in measuring and improving quality.

Using a survey of attitudes towards the newly revised clinical practice guidelines for rheumatoid arthritis, we investigated current provider opinions of rheumatology physicians defined as physicians whose practice is focused on rheumatic diseases, including rheumatologists, orthopaedic surgeons and some general physicians in Japan regarding which methods are desirable in evaluating the quality of rheumatoid arthritis care. We also analysed the relative degree of acceptance of process-of-care quality measurement among alternative methods of quality assessment.

Methods

Physician survey

We analysed data obtained from a larger survey conducted to evaluate the usefulness of the revised Japanese rheumatoid arthritis clinical practice guidelines [20,21] and rheumatology physicians' general attitudes towards clinical practice guidelines. Details of the survey are reported elsewhere [22]. Briefly, the survey was distributed to a random sample of rheumatology physicians registered with the Japan Rheumatism Foundation. This Foundation is an affiliate of the Japan College of Rheumatology, which plays a central role in supporting research and practice in rheumatology in Japan by funding programmes and disseminating up-to-date information to providers and patients. Eligibility to register with the Foundation is limited to physicians who have been focused on rheumatology practice for at least 5 years and are approved by the review committee based on documentation of cases they have cared for. They are typically but not exclusively rheumatologists and orthopaedic surgeons. The survey was conducted in two waves, the first in December 2002 and the second in March–April 2006. Only the second included questions related to quality of care, and thus the current analysis used this wave only.

Quality of care question item

Among questions about the rheumatoid arthritis guidelines and respondents' practice patterns, the second wave survey included

several items that asked about the quality of care in the framework of clinical practice guidelines. The main question asked respondents to rank proposed methods of assessing the quality of institution-provided rheumatoid arthritis care, namely patient satisfaction, risk-adjusted outcomes such as complication incidence and admission rate, guideline compliance, waiting time at clinics, voting by local general practitioners, degree of reportage by newspapers and magazines, and the volume of patients receiving treatment for rheumatoid arthritis. Tied rankings were not explicitly permitted but were treated as such if selected. Because this question of quality assessment was the focus of the present analysis, only respondents who answered this item were entered in the analyses.

Statistical analysis

To obtain a summarized group opinion, we report the modal rank and mean rank for each candidate quality assessment method. After ranking methods by mean rank, we then tested statistical differences in mean ranks between adjacently ranked methods (i.e. first versus second rank, second versus third rank, etc.) using the *t*-test.

Focusing on process measures as represented by guideline adherence, we further examined the relationship of respondent characteristics with the high ranking (i.e. first to third ranking among the proposed measures) of 'guideline adherence' as the quality measure. First, we described the proportion of respondents who ranked guideline adherence highly by stratifying physician characteristics, and then compared proportions using the chi-squared test. Second, we used a multivariable logistic regression to examine the independent association of these factors with the high ranking of guideline adherence. The examined factors included respondent gender, years in practice (<20 years/21–40 years/>41 years), specialty (surgeon/internists), patient volume (~10/11–20/21–30/31–40/≥41 patients for whom the respondents care regularly), type of practice setting (office practice/non-university hospital/university hospital), practice location (eastern/western Japan) and area type (metropolitan/urban/rural). Non-respondents to each item were excluded from the bivariate and multivariate analyses. An alpha level of 0.05 was used to decide statistical significance. The study protocol was approved by the Institutional Review Board of Kyoto University Graduate School of Medicine and Public Health.

Results

Among 1111 physicians surveyed in the second wave, 531 (48%) responded to the question about quality assessment and were entered into the analysis. Respondent characteristics are presented in Table 1; average age was 54 years (range 37–91), with 28 years in practice (12–64), and 5% were female.

Figure 1 shows the distribution of assigned rankings for each quality assessment method. Patient satisfaction was most favourably ranked, with a mean rank of 1.6, followed by complication rate (mean rank 2.7) and number of patients (mean rank 3.3). Guideline adherence was ranked mostly in the middle with a mode ranking of 4 (mean 4.0), which was about the same as that for voting by local physicians (mean rank 4.2). Assessment by waiting time and reportage in newspapers and magazines were considered

Table 1 Subject characteristics ($n = 531$) and percentages of respondents ranking 'guideline adherence' highly as a desirable quality measure

	n (%)	High rank for 'guideline adherence'	
Gender			$P = 0.90$
Female	27 (5)	33%	
Male	498 (95)	35%	
Years in practice			$P = 0.41$
<20	207 (39)	32%	
21–40	265 (50)	35%	
≥ 41	53 (10)	42%	
Specialty			$P = 0.68$
Surgeons	358 (70)	34%	
Internists/others	163 (30)	36%	
Number of rheumatoid arthritis patients (%)*			$P = 0.07$
≤ 10	104 (20)	41%	
11–20	100 (19)	34%	
21–30	82 (16)	40%	
31–40	54 (10)	37%	
≥ 41	184 (35)	27%	
Practice settings			$P = 0.34$
University hospital	62 (12)	29%	
Non-university hospital	205 (39)	33%	
Physician office	249 (47)	36%	
Other	11 (2)	55%	
Area type			$P = 0.66$
Metropolitan	149 (28)	34%	
Urban	318 (60)	33%	
Rural	61 (12)	39%	
Practice location			$P = 0.15$
Eastern Japan	218 (41)	37%	
Western Japan	313 (59)	31%	

*Does not add up to 100% because of rounding.

The following non-responding subjects were excluded: 6 subjects for gender and years in practice, 10 subjects for specialty, 4 subjects for practice setting, 7 subjects for number of rheumatoid arthritis patients and 3 subjects for area type.

unfavourable methods of assessment (mean rank of 6 and 6.1, respectively). The differences in mean rank between adjacently ranked methods were significantly different except for that between guideline adherence and voting by local physicians ($P = 0.14$) and between waiting time and reportage in the media ($P = 0.76$). This general ranking trend did not change on stratified analysis by working facility, place of practice, volume of patients or years in practice.

The exploration of factors related to the high ranking of guideline adherence in the unadjusted analysis is presented in the right columns of Table 1. None of the factors examined was associated with the high ranking of guideline adherence as a desirable quality measure. An exception was the number of rheumatoid arthritis patients for whom the respondent cares, which showed the non-significant trend that high-volume respondents with ≥ 41 regular patients were less likely to rank guideline adherence highly (overall $P = 0.07$). After adjustment for these factors using the logistic regression analysis, this group appeared significantly less likely to rank guideline adherence highly (odds ratio = 0.38 compared to the low-volume group with ≤ 10 regular patients, $P < 0.01$; Table 2). The Hosmer–Lemeshow test revealed that the model had a reasonable fit, with a P -value of 0.88.

Discussion

Our survey revealed a number of interesting points about Japanese rheumatology physicians' opinions on how the quality of care should be assessed. First, patient satisfaction is considered the best method of quality assessment, with this option ranked higher than other methods which target the technical aspects of care. The preference for this interpersonal quality over technical quality may indicate that the assessment of technical care is not considered to capture the 'true' technical quality of care. Alternatively, respondents may be reluctant to subject their practice to the physical and psychological intrusion of technical assessment.

Among the assessment methods targeting the technical aspect of care, the outcome measure of complication/admission rate was preferred over the process measure of guideline adherence. This finding stands in stark contrast to extensive use of process measures in western countries [4,7–9,11]. Because no nationwide quality assessment system for either outcome or process is implemented in Japan, the idea of using guidelines to assess quality may be difficult for the respondents to imagine. Furthermore, process measures used in practice are usually modified from the guideline recommendations themselves so that they can serve a measurement

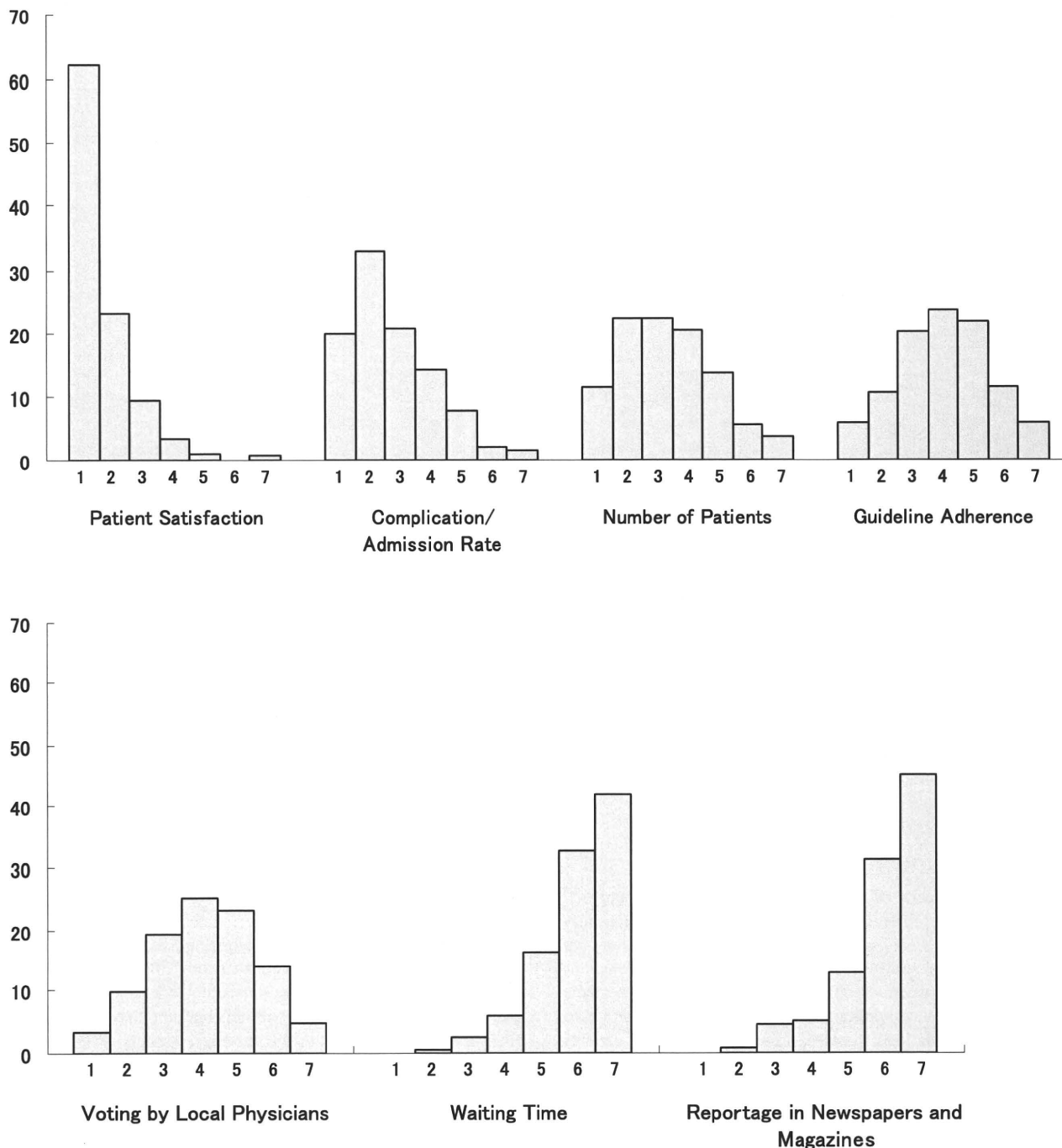


Figure 1 Ranking distribution of quality assessment methods for rheumatoid arthritis care.

purpose. Unfortunately, we suspect that the respondents had little experience or knowledge of process quality-of-care measurement, and concede that use of the term ‘guideline adherence’ to mean process measures in the questionnaire may have lacked precision. In any case, if guideline recommendations are to be used as quality indicators after pertinent modification, additional effort to convince physicians appears necessary, such as the convening of an expert

panel specifically commissioned to examine the validity of each recommendation as a quality indicator.

A second interesting point is that ‘number of patients’ was considered preferable to guideline adherence as a quality assessment. Although the volume–outcome or volume–quality relationship has been extensively studied in surgical and medical conditions [23], we are unaware of any study showing that

Table 2 Respondent factors in relation to a higher (first to third) ranking of guideline adherence as the quality measure

		Odds ratio (95% CI)	P-value*
Sex	Female (vs male)	0.78 (0.33–1.99)	0.60
Years in practice	(vs <20)		0.18
	21–40	1.25 (0.82–1.89)	
	≥41	1.85 (0.95–3.60)	
Specialty	Surgeons (vs others)	0.72 (0.45–1.13)	0.16
Working facility	(vs university hospital)		0.40
	Non-university hospital	0.87 (0.44–1.71)	
	Physician office	0.97 (0.49–1.92)	
	Other	3.25 (0.64–16.45)	
Number of rheumatoid arthritis patients	(vs ≤10)		0.01
	11–20	0.61 (0.34–1.11)	
	21–30	0.80 (0.43–1.47)	
	31–40	0.60 (0.29–1.22)	
	≥41	0.38 (0.22–0.67)	
Area (%)	(vs metropolitan)		0.68
	Urban	0.97 (0.62–1.51)	
	Rural	1.27 (0.64–2.50)	
Practice location	Eastern Japan (vs western)	0.71 (0.47–1.07)	0.10

*Overall P-values for categories.

larger-volume providers of rheumatoid arthritis care produce better outcomes. Because the strength of the volume–outcome relationship varies across surgery types [24], future research should test the opinion of rheumatology physicians, as identified in this survey, that volume is a good proxy of quality of care, which leads to better rheumatic care outcomes, or is at least a better proxy than explicit guideline adherence.

Guideline adherence was ranked almost the same as ‘voting by local physicians’, which is a popular method used by the media. The Best Hospitals report published by the US News is one of the most famous examples [25]. In Japan also, several books have used physician voting to evaluate hospitals [16,26]. In a sense, guideline adherence can be viewed as an evaluation using explicit technical criteria, while voting by local physicians is a form of implicit review of quality, if appropriately performed. However, implicit review is known to be unreliable in the absence of detailed instruction and pertinent training of the reviewers, and bias due to sub-optimal methodology is sometimes unclear.

Exploration of factors associated with the high ranking of guideline adherence revealed that high-volume respondents who care for >40 regular rheumatoid arthritis patients were less likely to rank guideline adherence highly. Because guidelines are sometimes criticized as ‘too cookbook’ [22], high-volume respondents who theoretically have more chance to care for atypical patients may feel less inclined to use guideline recommendations as quality standards. Other factors examined here were not significantly associated with ranking of guideline adherence.

Our results should be interpreted in view of several limitations. First, the survey was conducted among rheumatology physicians engaged in rheumatoid arthritis care, potentially limiting its generalizability to other conditions or types of physicians. Rheumatoid arthritis care is unique in that physicians need to select the most suitable of a wide range of anti-rheumatic medications (i.e. disease-modifying anti-rheumatic drugs) and biological agents and to fine-tune dosages to avoid adverse effects. This process is not only more complex and prolonged than that for most

other common diseases, but also highly individualized, limiting the value of guideline recommendations. Second, the ranking of candidate assessment methods reveals relative preference only. The physicians may have thought that patient satisfaction is merely ‘less bad’ than even worse methods and ranked it highly on this basis alone. We chose ranking to focus on the difference between candidate methods, and expect that future research will examine absolute preference for these potential methods. Finally, potential differences between respondents and non-respondents may have biased the results. The overall survey was about guidelines, and respondents may have had a more favourable attitude to guidelines than non-respondents. Although guideline adherence was ranked about in the middle, non-respondents might have rated this item even lower.

Despite these limitations, we found that Japanese rheumatology physicians consider that patient satisfaction is the best method for quality assessment, and presently do not fully accept guideline adherence as a standard criterion of quality. Efforts to gain the support of quality monitoring systems focusing on process of care from practising physicians and enable their smooth introduction should focus on ways to construct convincing methods of assessing the technical quality of rheumatoid arthritis care.

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Opinions of Japanese rheumatology physicians regarding clinical practice guidelines

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Abstract

Objective. To examine the views of rheumatology physicians concerning clinical practice guidelines in Japan, and changes to them following the dissemination of new guidelines for rheumatoid arthritis (RA) in 2004.

Design. Two cross-sectional questionnaire surveys, the first conducted before publication of new evidence-based RA clinical practice guidelines and the second conducted after implementation.

Setting. Rheumatology-focused practices in Japan.

Participants. A random sample of physicians registered with the Japan Rheumatism Foundation who satisfied the registration criteria with regard to experience with RA care.

Results. The percentage of guideline users increased from 48 to 60% following publication of the new RA guidelines in 2004 ($P < 0.01$). The majority agreed that clinical practice guidelines support decision-making in practice, although the proportion of supportive responses decreased slightly in the second survey, from 83 to 77% ($P < 0.01$) for decision-making, while concern about restricting physician autonomy increased from 18 to 22% ($P = 0.01$). While only 39% of physicians felt that clinical practice guidelines would contribute to malpractice litigation, the proportion of physicians who were concerned that clinical practice guidelines would be used to bring legal action against providers was larger than that who expected they would defend providers (58 vs 30%, $P < 0.001$).

Conclusions. Clinical practice guidelines are well accepted among Japanese rheumatology physicians, albeit that the proportion decreased slightly after the introduction of new guidelines. One reason for this may be concern about the use of the guidelines in malpractice litigation. To facilitate implementation, trends in physician support for the guidelines should be closely monitored.

Keywords: surveys, general methodology, guidelines, appropriate health care, rheumatoid arthritis

Introduction

Clinical practice guidelines are intended to improve health-care quality by providing both patients and practitioners with knowledge regarding current standards of care [1]. They typically summarize available evidence and provide specific recommendations in a wide range of clinical circumstances. Successful implementation of clinical practice guidelines

enables practices to remain up-to-date and assure physicians that their practices meet current standards.

While intended to aid in practice, however, clinical practice guidelines have also been shown to provoke mixed reactions among practicing physicians [2, 3]. Common criticisms include statements that guidelines oversimplify practice or are 'too cookbook.' Some physicians are concerned that the guidelines may be used to bring malpractice action against

physicians, while others feel that they threaten physician autonomy and the patient–physician relationship [4].

In 1999, the Japanese government began funding research groups connected with professional societies to support the development of clinical practice guidelines in various clinical areas [2, 3, 5, 6]. The Japan Rheumatism Foundation, an affiliate of the Japanese College of Rheumatology, took this opportunity to revise its RA guidelines, both then and presently the only RA guidelines in Japan developed by a professional RA association. The then-current guidelines, published in 1997, were based on an informal expert consensus rather than a systematic review of evidence. The 2004 revised version was the first RA guidelines in Japan to be formally drafted after a systematic review of the literature and evaluation of evidence [7, 8], and included information on new laboratory tests (e.g. antibodies to citrullinated protein antigen) and recommendations for disease-modifying anti-rheumatic drugs (DMARD) use early in the course of treatment.

Thanks to the Government's efforts [5], the development of clinical practice guidelines proliferated in many areas of medicine around this time. To ensure the implementation of guidelines, however, and the high-quality, evidence-based healthcare system they are designed to promote, it is important to understand how clinical practice guidelines are perceived and accepted in medical community. To examine the views and experiences of practicing physicians, and changes following the publication of new RA clinical practice guidelines, we surveyed practicing physicians registered with the Foundation before and after publication of the guidelines.

Methods

Sample subjects

We surveyed a sample of physicians randomly selected from among registered members of the Japan Rheumatism Foundation, an organization which supports rheumatology research and the education of rheumatology professionals and patients. Registered physicians included specialists in the treatment of rheumatic diseases such as rheumatologists and orthopedic surgeons, as well as general internists, among others. To be registered with the Foundation, physicians must have 5 or more years' experience in rheumatology practice and receive continuing medical education provided by the Foundation. Although the registered physicians are not necessarily rheumatology specialists with formal rheumatology training, they nevertheless provide care to rheumatology patients, and are hereafter referred to as 'rheumatology physicians.'

Survey instruments

Survey participants received packets of the survey instruments by postal mail in March 2003, before the 2004 publication of the new evidence-based clinical practice guidelines for rheumatoid arthritis (RA) care, and again in March 2006 after their publication [7]. The second survey was mailed out only to those physicians who responded to the first, and

included a copy of the new clinical practice guidelines to compensate respondents for their time and effort.

Questions that were common to both surveys inquired into overall attitudes and opinions regarding clinical practice guidelines and experience with RA guidelines, including the use in the respondent's personal practice and unprompted mention by patients. The second survey explored a wider range of perspectives by adding questions concerning the influence of clinical practice guidelines on practice and decision-making; expected usage of the guidelines in malpractice lawsuits; opinion regarding important characteristics of useful clinical practice guidelines and the expected effect of providing guidelines to patients and families. Attitudes toward guidelines and expected usage in malpractice lawsuits were evaluated using a five-level Likert scale of how strongly respondents agreed with the statement listed in the survey, namely strongly agree, somewhat agree, uncertain, somewhat disagree and strongly disagree. Important characteristics of useful clinical practice guidelines and the expected effect of providing guidelines to patients and families were asked by yes/no questions. The individual items are provided in the tables of survey results (Tables 2–5).

Statistical analysis

Categorical variable distribution was compared using a chi-square test, while continuous variables were compared using Student's *t*-test. Because the assumption of normal distribution was not satisfied for either age or years in practice, statistical differences were tested using the Kruskal–Wallis test. With regard to general opinions of clinical practice guidelines, responses were collapsed into two (positive and negative) or three categories (positive, uncertain and negative) for the purposes of presentation. Changes in the response to questions common to the first and second surveys were compared using statistical tests, while responses to questions listed only in the second survey were simply described. All analyses were performed using STATA version 10.1 (Stata Corp., College Station, TX, USA). The study protocol was approved by the Institutional Review Board of Kyoto University School of Medicine and Public Health.

Results

Respondent characteristics

Of the 2000 physicians initially approached, 1117 responded to the first survey, of whom 682 also responded to the second. Table 1 lists the characteristics of survey respondents. Mean respondent age was 50 years, and most were male (95%). Participants specialized in various fields, with about two-thirds being orthopedic surgeons. The only statistically significant difference observed between those responding to both surveys versus those responding only to the first was that the non-responders tended to treat fewer RA patients in their practice ($P = 0.04$).

Table 1 Characteristics of respondents and non-respondents to the 2006 survey among respondents to the first survey ($n = 1117$)

	Respondents ($n = 682$)	Non-respondents ($n = 435$)	P value ^a
Age in years, mean (SD) ^b	50 (10)	50 (10)	0.83
Male, % ^b	95	95	0.86
Years in practice, mean (SD) ^b	25 (10)	26 (11)	0.98
East Japan residents, % ^b	41	37	0.22
Practice area, %			
Metropolitan	28	28	
Urban	60	60	
Rural	12	12	0.98
No answer	1	0	
Specialty, %			
Orthopedic Surgeon	70	67	0.96
Internal Medicine	27	26	
No answer	3	7	
Practice size, % (n of continuous RA patients, %)			
≤ 10	20	27	0.04
11–20	20	20	
21–30	16	15	
31–40	11	11	
>40	34	27	
No answer	1	1	

^aChi-square test for categorical variables and Kruskal–Wallis test for continuous variables (due to violation of normality assumptions) for persons who provided answers. ^bSeven, 5, 10 and 3 respondents did not provide age, gender, years in practice or practice prefecture, respectively.

Experience with clinical practice guidelines

Table 2 describes respondents' experience with clinical practice guidelines. The proportion of rheumatology physicians who reported at least occasionally using the Japanese RA guidelines (always/three or more times per month or occasionally/about once a month) increased from 48 to 60% following publication of the new clinical practice guidelines. The percentage who used foreign rheumatology guidelines (use the original/familiar through Japanese review articles) did not change (33–32%), but use through reviews and sources other than the original rose from 18 to 21% (overall $P < 0.01$). The proportion of respondents who felt that the Japanese RA guidelines were very or sometimes useful increased from 62 to 69% ($P < 0.01$).

General attitude toward clinical practice guidelines

General attitudes toward clinical practice guidelines are presented in Table 3. Most respondents stated support for clinical practice guidelines, with 83 and 77% in the 2003 and 2006 surveys agreeing that they support decision-making in practice, and 91 and 89% agreeing that they are useful for medical education, respectively. A minority of respondents in both surveys agreed with negative sentiments that clinical practice guidelines restrict physician autonomy and oversimplify clinical medicine (32 and 35% in each survey). In questions appearing

only in the 2006 survey, guidelines were generally believed to aid in sharing information with patients (56%), while a larger proportion felt that they should be available to the general public (46 agreed versus 15% disagreed, $P < 0.01$). Although general attitudes to clinical practice guidelines did not notably change before and after publication of the new clinical practice guidelines, the prevalence of positive opinions decreased slightly (e.g. support decision-making, 83–77%, $P < 0.01$) while that of negative opinions increased slightly (e.g. restrict physician autonomy, 18–22%, $P < 0.01$).

The 2006 survey contained several questions about guidelines and quality of care. Although 94% of respondents agreed that experts should know the contents of clinical practice guidelines, only 51% supported the idea that actual adherence to guidelines is an important indicator of quality. Further, only 37% agreed that a reason should be documented in situations in which guideline recommendations are not followed, although this percentage was larger than the 25% who actively disagreed with the necessity of documentation.

The lower part of Table 3 highlights the physician views from the 2006 survey regarding the influence of clinical practice guidelines on malpractice lawsuits. Thirty-nine percent of respondents felt that clinical practice guideline publication might lead to an increase in malpractice lawsuits. Further, more respondents (58%) felt that clinical practice guidelines would be used to bring legal action against physicians than reported that guidelines would be used to defend them against such actions (30%).

Table 2 Experience and opinions regarding RA guidelines ($n = 682$)

	Survey 2003	Survey 2006	<i>P</i> value ^a
Use of Japanese RA guidelines, % ^b			
Always or three or more times per month	10	21	<0.01
Occasionally or about once a month	38	39	
Seldom	32	21	
Aware of the guidelines but never used	14	16	
Not aware of the guidelines	5	2	
No response	2	1	
How useful are Japanese RA guidelines?, %			
Very useful	14	19	<0.01
Sometimes useful	48	50	
Uncertain	14	16	
Seldom or never useful	5	5	
Don't use	18	10	
No response	2	0	
Use of guidelines from other countries, %			
Use the original	15	11	<0.01
Familiar through Japanese review articles	18	21	
Wish to use, but never used	30	23	
Irrelevant to practice in Japan	8	11	
Never thought about usefulness	24	30	
No response	5	4	
How useful are RA guidelines published in other countries?, % ^b			
Very useful	13	12	0.97
Sometimes useful	42	44	
Uncertain	30	32	
Not useful	2	2	
No response	13	9	
Do patients mention guidelines?, % ^c			
Sometimes	—	1	
Once in a while	—	7	
Seldom/never	—	89	
No response	—	3	

^aChi-square test for persons who provided answers. ^bAsked only to those who used clinical practice guidelines from other countries.

^cQuestion added in the second survey.

Clinical practice guidelines and patients

The 2006 survey contained questions about patients and guidelines. The results showed that patients rarely mention clinical practice guidelines. Most respondents (about 90%) reported that patients seldom or never mentioned clinical practice guidelines (Table 2). More than half felt positively about providing guidelines to patients and families, considering that they would help them (Table 4). A minority were concerned about patient ability to understand the guidelines.

Opinions regarding important characteristics of clinical practice guidelines

Table 5 details characteristics that respondents felt were important to include in clinical practice guidelines, based on

questions in the 2006 survey only. Eighty percent felt that clearly stating the reasons for guideline recommendations was important, while a somewhat smaller percentage (61%) felt that discussing the validity of clinical evidence was important. Fewer respondents placed import on aspects of the development process, including the specification of aims (48%) and presentation of the results of external review (42%). Only 20% of respondents felt it was important to state conflicts of interest.

The 2006 survey also inquired into awareness of the formal evaluation instrument developed by the Appraisal of Guidelines for Research and Evaluation (AGREE) collaboration [9]. Only 10% of the respondents were aware of the contents of this instrument, while 32% reported that they had at least heard of the name. More than half, however, had never heard of the instrument (55%).

Table 3 Physician opinions of clinical practice guidelines (*n* = 682)

Survey year	2003				2006				<i>P</i> value ^b
	Strongly agree/ %, ^a	Uncertain, %, ^a	Disagree/strongly disagree, % ^a	Strongly agree/ %, ^a	Strongly agree/ %, ^a	Uncertain, %, ^a	Disagree/strongly disagree, % ^a	Strongly agree/ %, ^a	
General attitudes toward practice guidelines									
Guidelines support decision-making in practice	83	14	2	77	18	4	4	18	<0.01
Guidelines support medical education	91	6	2	89	14	9	9	14	0.19
Guidelines restrict physician autonomy	18	31	50	22	36	42	42	36	0.01
Guidelines aim for cost containment	22	46	31	14	47	38	38	47	<0.01
Guidelines oversimplify clinical medicine	32	35	32	35	35	29	29	35	0.48
Guidelines should be promoted in various clinical areas	60	32	8	51	36	11	11	36	<0.01
Guidelines facilitate sharing information with patients	—	—	—	56	32	11	11	32	
Guideline contents should be available to the general public	—	—	—	46	38	15	15	38	
Experts should know the guideline content	—	—	—	94	5	1	1	5	
Guideline adherence is an important indicator of quality	—	—	—	51	37	12	12	37	
Justification should be documented when not following recommendations	—	—	—	37	37	25	25	37	
Perception toward guidelines in the context of malpractice litigation									
Publication of guidelines will lead to an increase in malpractice lawsuits	—	—	—	39	42	16	16	42	
Guidelines will be used to bring legal action against medical providers	—	—	—	58	31	9	9	31	
Guidelines will be used to defend medical providers against legal action	—	—	—	30	47	21	21	47	

^aNon-responses were less than 3%, and not included in the percentage. ^bComparing distribution pre- and post-publication of the new RA guidelines.

Table 4 Agreement with statements about effects of guidelines on patients (2006 survey, $n = 682$)

Statement	Agree, %
Guidelines will help the process of informed choice	53
Guidelines will help provide knowledge to patients and families	55
Additional materials besides guidelines are necessary for full understanding	39
Guidelines will confuse patients and families	24

Table 5 Physician opinions regarding important characteristics of guidelines (2006 survey, $n = 682$)

Feature	Agree, %
Reasons for recommendations are clearly stated	81
Discussion of validity of evidence in the literature	61
Guideline aims are clearly specified	48
External review results are presented	42
Developed by trustworthy organization or persons	38
Uniform format for each recommendation	29
Conflict of interests of the persons involved are specified	20

Discussion

This study found that the new RA clinical practice guidelines were generally accepted by rheumatology physicians in Japan, with about 60% reporting that they used them and a majority reporting that they were useful. The proportions of both increased after publication. A majority also felt that clinical practice guidelines in general support clinical practice and are useful in medical education, and that experts should know the contents of guidelines. Most also supported the development of clinical practice guidelines in clinical areas outside of RA. Overall, the survey revealed that the number of physicians who at least occasionally use the Japanese RA guidelines has increased, providing further evidence to indicate support for guideline use.

Our results showed that Japanese rheumatology physicians have a comparable or greater support for clinical practice guidelines than the average level reported in a systematic review by Farquhar *et al.* [4] of surveys conducted in 1990–2000. They found that the percentages of respondents who regarded clinical practice guidelines as helpful sources of advice and as good educational tools were 75 and 71%, respectively, versus 77 and 89% in our 2006 survey. Further, the negative views represented by the proportion of respondents who felt that clinical practice guidelines restrict

physician autonomy or oversimplify clinical medicine were comparable or smaller than the average in Farquhar's review (22 and 35%, respectively, in our 2006 survey, versus 34% overall in the reviewed surveys). The large number of positive opinions in the present study may be attributed to underlying trust with the RA guidelines, which were issued by the Japan Rheumatism Foundation, to which the all respondents belonged. In addition, the studies included in Farquhar's review were all conducted in Western countries and none were focused on rheumatology physicians. Future research may need to address how these differences in settings and samples lead to differences in attitudes toward guidelines. Another explanation may be that the study was conducted during a period in which clinical practice guidelines proliferated in many clinical areas in Japan, fueled by a government initiative [5]. Guideline support has hopefully contributed to support for the periodic revisions which are generally necessary every 3 to 5 years [10].

The minority of non-support for the guidelines is not attributable to respondent preference for western over Japanese guidelines. Since both the Japanese and international guidelines base their recommendations on a similar set of evidence found on extensive literature review [7, 8], there was no major discrepancy between them in direction. Nevertheless, the Japanese guidelines clearly reflect particular characteristics of the Japanese healthcare system and practice environment. An example is that Japanese national insurance does not cover methotrexate as a first-line drug for RA, but rather only as second-line or later drug. The Japanese guidelines acknowledge this restriction in the section for DMARDs. They also mention domestically developed DMARDs such as bucillamine, actarit, mizolibine and lobenzarit, and acknowledge that evidential support of efficacy from large-scale randomized controlled trials is lacking.

Of some concern is the fact that the number of rheumatology physicians who expressed positive views towards clinical practice guidelines decreased over time, while those expressing negative views increased. Between the first and second surveys, for example, the percentage of respondents who felt that guidelines support decision-making in practice decreased from 83 to 77%, while the percentage who felt that they restrict physician autonomy increased from 18 to 22%. One explanation may be the dramatic change in rheumatology practice occurring between publication of the revised guidelines and the second survey with the advent of biological agents such as infliximab. This may have made many physicians feel that the guideline was already outdated at the time of the second survey. Another explanation is that these small changes simply reflect over-expectations before the arrival of the new guidelines, or regression to the mean if those who had more positive attitudes than the average practicing physician were more likely to have responded to the first survey. Future research should closely monitor clinician opinions regarding clinical practice guidelines.

Reports of patient use or mention of clinical practice guidelines were rare, possibly due to the unavailability of patient-use Japanese RA guidelines at the time of the survey. The first patient-use guidelines for RA were published in

June 2006, immediately after the survey was completed, and the number of patients who read the guidelines is therefore expected to increase. Physicians generally expect that clinical practice guidelines will exert a beneficial influence on patients and families. Physician experience with patient mention of guidelines during clinical visits bears further investigation.

Although only a minority of respondents felt that clinical practice guidelines restrict physician decision-making, a substantial proportion expressed concern regarding malpractice lawsuits. Further, many physicians felt that clinical practice guidelines might be more often used as a basis for bringing legal action for malpractice than as a defense against such action, despite the explicit assertion within the new Japanese RA guidelines that they should not be used to set standards for malpractice lawsuits [7, 8]. This concern is compounded by a somewhat outdated study regarding medical malpractice insurance claims from the USA, which reported that clinical practice guidelines are more often used for inculpatory rather than exculpatory purposes [11]. Moreover, while Japan entertains relatively few malpractice lawsuits, with an annual filing of 944 in 2007, this number was nevertheless rising rapidly until 2005, after which it decreased slightly [12, 13]. Since legal pressure may be more likely to promote defensive practice and increase malpractice insurance premiums than improve quality of care [14], implementation of mechanisms to prevent the abuse of clinical practice guidelines may be necessary.

Overall, most clinicians appeared to be unfamiliar with the AGREE criteria [9], which focus on the methodological appraisal of clinical practice guideline quality. Further, some aspects of the criteria set did not seem important to many clinicians. Clinicians naturally placed emphasis on the logic which underpinned recommendations, such as adequate search for evidence and a clear statement of reasoning. Only a minority of physicians, however, regarded statements of conflict of interest and external review as important, both of which are included in the AGREE criteria. This may be because the use of clinical practice guidelines is not particularly common in Japan, and thus many clinicians have never experienced obviously biased recommendations due to these factors, or been forced to choose among multiple clinical practice guidelines for the same area. Further, given that guidelines are meant to facilitate decision-making rather than dictate clinical practice, decision-makers must judge for themselves the validity of any guideline-directed recommendation. A conflict of interest statement itself does not necessarily guarantee or provide evidence of the validity of an individual recommendation. Given the variation in perceived importance across factors, the exploration of weighting systems in AGREE instruments may be of interest, perhaps based on user opinion.

The present study should be interpreted within several limitations. First, the response rate was not high. Physicians who support clinical practice guidelines may have been more likely to respond than those who do not, resulting in overstatement of support for guidelines. Although we have no information on non-respondents to the first survey, respondents to the second did not substantially differ from those responding to the first only. Second, our survey sample was rheumatology

physicians, who may differ from physicians in other specialties. The generalizability of the results should be interpreted within this sampling framework. Finally, positive views of clinical practice guidelines do not necessarily lead to the use of such guidelines, and self-reporting of use may not be accurate. A more accurate understanding of guideline use and adherence would require a review of medical records or insurance claims, or the direct observation of clinical encounters.

In conclusion, our survey revealed that clinical practice guidelines are generally accepted by Japanese RA physicians. This overall positive view is supportive of the implementation of the clinical practice guidelines in practice. While placing little attention on some procedural aspects of guideline development, such as conflict of interest and external review, clinicians do seem to consider the points necessary to evaluate recommendations on a case-by-case basis. Some decline in general support for guidelines was observed, possibly due to concerns about their use in malpractice litigation. Close monitoring of trends in guideline support should facilitate implementation in actual practice.

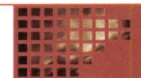
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Keeping vulnerable elderly patients free from pressure ulcer is associated with high caregiver burden in informal caregivers

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Keywords

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Abstract

Rationale and objectives The effect of the presence of pressure ulcers on burden of caregivers is unknown. We investigated the relationship between the state of pressure ulcers in vulnerable elderly patients and the burden on their informal caregivers.

Methods This cross-sectional study enrolled 137 patients aged ≥ 40 years with limited activity and mobility at 10 home care service facilities in Japan. We assessed pressure ulcer status from medical records and caregiver burden using scores from both the Burden Index of Caregivers (BIC) and the Japanese short version of the Zarit Burden Interview (ZBI).

Results Among patients, mean age was 80.9 years, 31.4% were men, and 83.9% were free from pressure ulcers. Multivariable analysis showed that caregivers whose patients were free from pressure ulcers had significantly higher caregiver burden as assessed by both the BIC [β -coefficient = 3.18, 95% confidence interval (CI): 1.42–4.95, $P = 0.003$] and ZBI scores (β -coefficient = 1.94; 95%CI = 0.30–3.58; $P = 0.03$).

Conclusions Our results suggest that the continuous effort involved in keeping patients free from pressure ulcers may be associated with high caregiver burden in informal caregivers.

Introduction

The number of elderly patients requiring care is increasing in many countries as a development of the aging of society. In the UK, the number of people aged over 65 with various chronic diseases and disabilities is projected to increase two- to three-fold in the next 70 years [1]. Of these, a considerable number of bedridden patients have been provided care at home by their families, namely 'informal caregivers'. A recent report suggested that a higher burden on informal caregivers was associated with

risk of death: caregivers experiencing caregiver strain had mortality risks that were 63% higher than non-caregiving controls [2].

Several studies have revealed relationships between the burden of care and social characteristics in several disease-specific populations [3–5]. Caregiver burden was defined by Zarit as the extent to which caregivers perceived that their emotional or physical health, social life and financial status suffered as a result of caring for their relative [6]. Therefore, caregiver burden must be measured from various aspects aimed at revealing the

multidimensional relationship between caregiver burden and the health status of both caregivers and their patients [7,8].

To date, however, no studies have examined the relationship between diseases or symptoms commonly observed in vulnerable elderly patients, such as aspiration pneumonia and pressure ulcer, and their burden of care. In particular, pressure ulcer is a significant health problem among vulnerable elderly patients mainly due to increased morbidity, increased health-related costs and reduced patient quality of life [9,10]. In home care settings, pressure ulcers appear a more serious problem because informal caregivers are continuously required to prevent them [11,12]. It is therefore worthwhile to quantitatively ascertain the caregiver burden of vulnerable patients with a higher risk of pressure ulcer.

Here, we investigated the relationship between the state of pressure ulcer in vulnerable elderly patients and the burden of care as assessed using scores from both the Burden Index of Caregivers (BIC) and the short version of the Japanese version of the Zarit Burden Interview (ZBI), based on data from a multicenter survey of vulnerable home care patients in Japan.

Methods

Study subjects

The target population was vulnerable elderly patients in 10 facilities (total $n = 801$) providing home care service in Kyoto, Japan. Participation was limited to patients showing limitations in activity and mobility (score for either of 1 or 2 in the Braden scale) and those who received care at home from related informal caregivers [13]. Those who became patients due to attempted suicide were excluded on the basis that their burden of care was considered to differ from those of other patients. Participants were recruited in accordance with these criteria from all patients of the 10 facilities. Patients aged less than 40 years were also eliminated because Japanese care insurance is intended for those aged 40 years or more. The study was approved by the institutional review board of Kyoto University, Kyoto, Japan.

Pressure ulcer assessment

The main variables evaluated were the state of pressure ulcer and the degree of caregiver burden. In the present study, information about pressure ulcers was derived from medical records. We defined the presence of pressure ulcer according to the pressure ulcer staging system of the National Pressure Ulcer Advisory Panel and included those categorized as Stage II or worse, representing at least a partial-thickness loss of the dermis [14]. Care need was evaluated according to the national index of long-term care need on a 6-point Likert scale derived from questionnaires regarding various aspects of patient health, including daily activity, episodes of incontinence, and nutritional status [15]. To estimate Japanese care insurance needs, the index was ultimately determined by the patient's local municipal review board of home care experts, including doctors, nurses and care workers.

Caregiver burden measurement

In the present study, a caregiver was defined as a person having a familial relationship with a patient and who most frequently

provided informal care in each family. Caregiver burden was assessed using the BIC, a recently developed 11-item multidimensional questionnaire validated against the Short Form-8 (SF-8) and ZBI which is considered highly reliable among caregivers providing home health care to patients with various conditions [8]. SF-8 is a short form of the health-related quality of life scale SF-36, and the ZBI is a 22-item care burden scale in frequent use throughout the world. The BIC has two novel domains, 'service-related burden' and 'existential burden', in addition to ordinary concepts about burden of care, and is designed to enable the precise measurement of the particular circumstances of Japanese care settings. Another advantage of the BIC is that its small number of items is not considered burdensome to respondents, in contrast to most other scales which have more items than BIC [7,16]. For both the BIC and ZBI, higher scores represent greater caregiver burden.

Statistical methods

The relationship between the state of a pressure ulcer and BIC score was examined using multivariable linear regression analysis. Models were adjusted for patient age, patient gender, caregiver age, caregiver gender, family relationship, daily estimated time for caregiving, national index of long-term care need, presence of Alzheimer-type dementia, and history of violence by patients within past 3 months.

Additionally, to assess the robustness of our results, we used the short version of the Japanese version of the ZBI, an eight-item questionnaire validated with the full version of the ZBI. Multivariable linear regression was also employed to compare with the state of pressure ulcers and ZBI score, adjusted for the same possible confounders as mentioned above [16,17].

Furthermore, subgroup analysis was performed in patients free from pressure ulcers. Multivariable linear regression analysis was used to examine the relationship between airmat use and BIC score, with adjustment for the same possible confounders mentioned above.

A multiple imputation approach using a chained equations method was employed to account for missing items of the BIC, ZBI and other confounding factors [18,19]. Among the total data, 0.9% of BIC items, 0.6% of ZBI items and 1.3% of confounders had missing values. Student's *t*-test was used for all other univariate analyses. Linear regression models took into account cluster effects at the facility level. All analyses were performed using STATA version 9.2 (StataCorp LP, College Station, TX, USA).

Results

Of 178 patients who fulfilled the inclusion criteria, 28 declined enrolment and 13 agreed but did not complete the questionnaire, leaving 137 patients (77.0%) finally included in the present study. Table 1 shows patients and caregivers characteristics, categorized by the state of pressure ulcer. The 137 patients had a mean age of 80.9 years, 31.4% were men, and 83.9% were free from pressure ulcer. Caregivers had a mean age of 65.0 years, 29.2% were men, and the mean duration of caregiving was 6.58 years.

Table 1 Baseline patient and caregiver characteristics classified by the state of pressure ulcer. Values represent sample means (SDs)

Characteristic	Patients free from pressure ulcer (<i>n</i> = 115)	Patients with pressure ulcer (<i>n</i> = 22)
Patient age, years (SD)	80.9 (11.3)	80.8 (13.6)
Patient gender, male, %	33.0	32.7
Caregiver age, years (SD)	65.4 (10.5)	62.6 (9.3)
Caregiver gender, male, %	25.2	50.0
Family relationship, caregiving spouse, %	38.3	27.3
Family relationship, caregiving parents, %	46.1	63.6
Daily estimated time for caregiving, hours (SD)	7.34 (5.55)	7.49 (5.68)
National index of long-term care need, grade (SD)	4.42 (0.91)	4.50 (0.96)
Neurodegenerative disorder, %	13.1	18.2
Alzheimer-type dementia, %	13.0	22.7
Violence by patients within past 3 months	6.71	13.6

Table 2 Factors associated with total Burden Index of Caregivers score using a multivariable linear regression model (*n* = 137)

Characteristic	β -coefficient	95% confidence interval	<i>P</i> -value
Free from pressure ulcer (vs. with pressure ulcer)	3.18	1.42 to 4.95	0.003
Patient age, per 1-year increase	-0.02	-0.16 to 0.12	0.72
Patient gender, female (vs. male)	0.42	-4.69 to 4.78	0.98
Caregiver age, per 1-year increase	-0.09	-0.24 to 0.22	0.93
Caregiver gender, female (vs. male)	-0.02	-2.78 to 2.74	0.99
Family relationship, spouse (vs. others)	1.56	-4.08 to 7.20	0.54
Daily estimated time for caregiving, per 10-hour increase	0.56	-1.23 to 2.34	0.54
National index of long-term care need, the severest grade (vs. other grades)	-1.58	-3.50 to 0.34	0.09
Alzheimer-type dementia (vs. no)	2.12	-3.95 to 8.18	0.44
Violence by patients within past 3 months (vs. no)	7.15	4.45 to 9.84	<0.001

Relationship between the state of pressure ulcer and the care burden of informal caregivers

Results for total BIC score were 14.2 and 17.9 for those with pressure ulcer and those who were free from pressure ulcer respectively. Figure 1 shows the rate of patients who were free from pressure ulcers, categorized into tertiles by BIC score, indicating a dose-dependant relationship between the state of pressure ulcers and caregiver burden.

In multivariate analysis, caregivers whose patients were free from pressure ulcer had significantly higher BIC scores than those of patients with pressure ulcer [β -coefficient = 3.18, 95% confidence interval (CI): 1.42–4.95, *P* = 0.003] (Table 2).

With regard to the ZBI as the scale of caregiver burden, multivariable analysis revealed that caregivers whose patients were free from pressure ulcer were likely to have a higher ZBI score (β -coefficient = 1.94, 95%CI: 0.30–3.58, *P* = 0.03).

Subgroup analysis

After excluding patients with pressure ulcers (*n* = 115), results for total BIC score were 19.2 and 16.8 with and without airmat use respectively. Multivariate analysis showed that caregivers who prepared airmats for their patients had significantly higher BIC

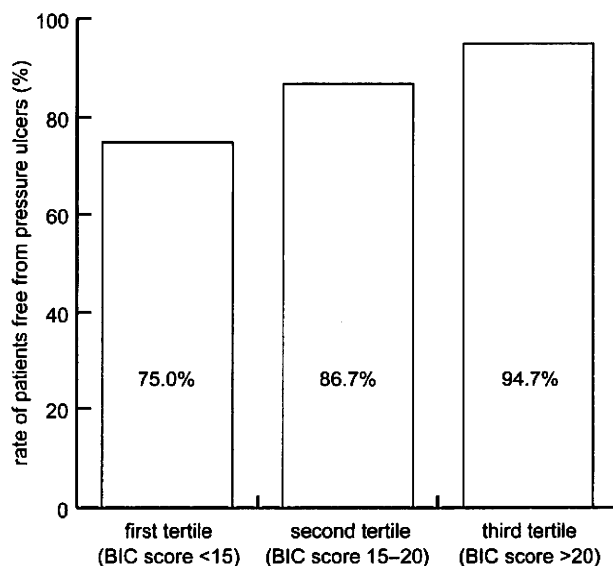


Figure 1 The rate of patients free from pressure ulcers in each subgroup categorized according to tertiles of the Burden Index of Caregivers (BIC) score.