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Ⅶ　研究成果の刊行物・別刷

Health and Quality of Life Outcomes

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Review

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Quality of life assessment and reporting in randomized controlled trials: a study of literature published from Japan

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Published: 25 June 2004

Health and Quality of Life Outcomes 2004, 2:31 doi:10.1186/1477-7525-2-31

Received: 12 February 2004
Accepted: 25 June 2004

This article is available from: http://www.hqlo.com/content/2/1/31

Abstract

Background: Standardization of quality of life (QOL) assessment and reporting in clinical trials is an imperative issue. While English-speaking countries have led this movement in standardization, there persists to be a limited amount of information from non-English-speaking including Japan. In this study, we bibliographically analyze the reporting of randomized controlled trials (RCT) conducted in Japan that used a QOL instrument.

Methods: A PubMed search of reports published between 1970–2003 followed by an examination of QOL reporting and its frequency of use in RCTs published from Japan.

Results: Percentages of QOL reporting in RCTs have increased between 1970–2003 both worldwide (0% for 1970–1974 to 4.4% for 2000–2003) and in Japan (0% to 1.8% for the identical periods). We found and evaluated 46 RCT reports published from Japan (32 in English, 14 in Japanese). The most commonly studied clinical condition was cancer (26, 56.5%) and the most common intervention was drug therapy (29, 63.0%). QOL was used as the primary endpoint in 10 studies (21.7%). Authors used established QOL instruments in 12 studies (26.1%), developed original instruments in 8 studies (17.5%) and assessed the symptoms or performance status in 10 studies (21.7%). Authors conceptually defined QOL in only 6 studies (13.0%). Neither response rate nor number of respondents for questionnaire surveys was specified in 16 studies (34.8%); furthermore, 11 studies (23.9%) did not describe respondents' attributes.

Conclusions: Findings on relative frequency suggested that Japanese authors of RCT reports have less interest in QOL instruments than other international researchers in Western Europe and North America. Examination of RCT reports published from Japan revealed that there were several points to be improved in reporting QOL instruments. This study highlights the need to define QOL measures specific to clinical specialty and to examine methodology for assessing and reporting QOL.

Background

During the past two decades, ideas of health have transformed from ones that focus on illness to ones that consider patient well-being and quality of life (QOL) [1,2]. Currently, QOL instruments that integrate clinical and economic indices serve as a key to understanding

treatment outcomes [2,3]. As Spilker defines, "'Quality of life' in clinical medicine represents the functional effect of an illness and its consequent therapy upon a patient as perceived by the patient [4]." Although randomized controlled trials (RCT) generally have the objective of evaluating intervention effect (i.e. drug, modes of care), significant results are not recognized unless a suitable measure of outcome is evaluated [5-7]. Accordingly, the use of QOL assessment as an outcome measure in RCTs continues to gain attention.

While the CONSORT statement [8] establishes methods of RCT reporting, this guideline does not address problems with QOL instruments, standards of cultural validity and psychometric validity. Sanders et al. [9] studied QOL assessment in clinical trials, indicating a high frequency of incomplete responses and a poor quality of reporting. Findings described a need for specified standards of QOL assessment and reporting. In 2002, international standards for QOL assessment and reporting in clinical trials were proposed [10]. But the fact that QOL is culturally influenced [4] reminds us that standardization based on information having originated from English-speaking countries may be impetuous. Accordingly, an examination of QOL-assessment methodology in RCTs collected from nations worldwide could provide valuable insight into the ramifications of standardization.

A PubMed-based bibliographical search found approximately 4000 reports on clinical trials published in Japanese between 1987 and 2001; this ranks second to German-published reports in number of non-English articles [11]. When limited to RCTs, the number of articles published between 1995 and 1999 from Japanese institutions ranks top amongst Asian nations and within the top ten internationally [12]. An understanding of how QOL is assessed in Japanese clinical trials, particularly in RCTs, will contribute to the ongoing international discussion.

In this literature study, we calculate the number of RCT reports that refer to QOL and compare Japanese publication trends with international ones. We then examine all reports published from Japan as of 1970. Based on our findings, we point to several imperative problems concerning the assessment and reporting of QOL that require further examination.

Methods

We performed a literature search of reports published between 1970–2003 using PubMed. We first located articles reporting RCTs by using "randomized controlled trial" as a PubMed "publication type s [pt]" tag – this was also used as a denominator to gain relative frequency. Second, we identified RCTs that referred to QOL by using the free text term "quality of life". For each year, we calculated the proportion of reports mentioning QOL among all RCTs.

Third, we looked for RCTs published from Japan that referred to QOL as follows: "randomized controlled trial" [pt] AND "Quality of life" [text] AND (Japan [address] OR Japanese [language]). Results were not only examined by frequency of reporting, but were also assessed by hand in more detail. Reviews, editorials, meeting abstracts, letters and publications without abstracts were excluded from the latter analysis.

Items of evaluation were based on previous reports [9,13,14] and included: (1) type of subjects' condition; (2) type of intervention tested; (3) type of QOL measures used and whether they were validated; (4) whether QOL was defined conceptually; (5) reasons why QOL measurement was introduced into the trial; (6) whether QOL was categorized as the primary or secondary endpoint and description of (7) the response rate and, lastly, (8) respondents of QOL measurements. Two of the authors independently evaluated all articles for eligibility and resolved disagreements by consensus. In cases when information on QOL-instrument validation was not mentioned in the article, we verified what type of validation study was conducted by checking references.

Results

Counting the number of articles with "publication type" and a free text term, frequency of referring to QOL was found to increase over time worldwide – from 0 (0%) between 1970–1974 to 1930 (4.4%) between 2000–2003. This trend was similar among reports published from Japan with 0 (0%) in 1970–1974 to 27 (1.8%) in 2000–2003 (Figure 1).

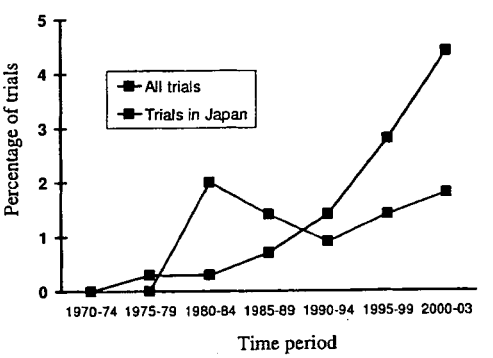

Figure 1
Prevalence of reporting on QOL in randomized controlled trials during 1970–2003

Table 2: Subjects studied in 46 randomized controlled trials reporting on QOL

	Number of trials (%)		
Subjects	English Reports	Japanese Reports	Total
Oncology	15 (46.9)	11 (78.6)	26 (56.5)
Cardiovascular diseases	5 (15.6)	0 (0.0)	5 (10.9)
Urology	4 (12.5)	2 (14.3)	6 (13.0)
Gastrointestinal diseases	3 (9.4)	1 (7.1)	4 (8.7)
Respiratory	2 (6.3)	0 (0.0)	2 (4.3)
Dentistry	1 (3.1)	0 (0.0)	1 (2.2)
Infection	1 (3.1)	0 (0.0)	1 (2.2)
Health*	1 (3.1)	0 (0.0)	1 (2.2)
Total	32 (100.0)	14 (100.0)	46 (100.0)

* Health is defined here as the effect of captopril during exercise

Table 3: Type of intervention studied in 46 randomized controlled trials reporting on QOL

	Number of trials (%)		
Intervention	English Reports	Japanese Reports	Total
Drug	18 (56.3)	11 (78.6)	29 (63.0)
Mode of care	9 (28.1)	3 (21.4)	12 (26.1)
Psychological	1 (3.1)	0 (0.0)	1 (2.2)
Immunotherapy	1 (3.1)	0 (0.0)	1 (2.2)
Hormone therapy	1 (3.1)	0 (0.0)	1 (2.2)
Radiotherapy	1 (3.1)	0 (0.0)	1 (2.2)
Rehabilitation	1 (3.1)	0 (0.0)	1 (2.2)
Total	32 (100.0)	14 (100.0)	46 (100.0)

65 RCT reports referring to QOL, published from Japan during 1970–2003, were found. We excluded 19 of these for not being RCTs (n = 4), not having an abstract (n = 1), not reporting on QOL (n = 12) or for being a review article (n = 2). The remaining 46 reports (32 were written in English and 14 were written in Japanese) met our criteria and were evaluated (Table 1 [see additional file 1]). Table 2 and Table 3 show the distributions of conditions and interventions examined and the language of each article. The most commonly studied condition was oncology (15 English reports; 11 Japanese reports; 26 in total, 56.5%), followed by cardiovascular disease (5 English reports; 0 Japanese reports; 5 in total (10.9%)) and urologic disorders (4 English reports; 2 Japanese reports; 6 in total, 13.0%), with other diseases occurring in less than 10% of reports (Table 2). The largest number of interventions was with drugs (18 English reports; 11 Japanese reports; 29 in total, 63.0%) followed by modes of care (9 English reports; 3 Japanese reports; 12 in total (26.1%)); other interventions were studied in less than 5% of reports (Table 3).

QOL was the primary endpoint in 10 reports (7 English reports; 3 Japanese reports; 10 in total, 21.7%). Only one report used a generic health-related QOL instrument. Authors defined QOL in 15 reports (9 English reports; 6 Japanese reports; 15 in total (32.6%)) (Table 4). Of these, authors of 9 reports (5 English reports; 4 Japanese reports; 9 in total, 19.6%) described their own definitions of QOL. After 1999, there were no RCT reports in Japanese that had investigators' definition of QOL.

A rising trend was recognized for reports describing why they performed a QOL assessment (Table 5) – prior to 1993, 2/7 reports (1 English report; 1 Japanese report; 2 in total (28.6%)); between 1994–1998, 6/14 reports (2 English reports; 4 Japanese reports; 6 in total (42.9%));

Table 4: Definition of QOL in 46 randomized controlled trials reporting on QOL

	Number of trials						
	Before 1993		1994–1998		1999–2003		Total
	English Reports	Japanese Reports	English Reports	Japanese Reports	English Reports	Japanese Reports	
Investigators' definition of QOL	0 (0.0)	1 (25.0)	1 (12.5)	1 (16.7)	3 (14.3)	0 (0.0)	6 (13.0)
General definition of QOL	0 (0.0)	0 (0.0)	1 (12.5)	2 (33.3)	4 (19.0)	2 (50.0)	9 (19.6)
No definition	3 (100.0)	3 (75.0)	6 (75.0)	3 (50.0)	14 (66.7)	2 (50.0)	31 (67.4)
Total	3 (100.0)	4 (100.0)	8 (100.0)	6 (100.0)	21 (100.0)	4 (100.0)	46 (100.0)

Table 5: Description of why QOL assessment was conducted in 46 randomized controlled trials reporting on QOL

	Number of trials						
	Before 1993		1994–1998		1999–2003		Total
	English Reports	Japanese Reports	English Reports	Japanese Reports	English Reports	Japanese Reports	
Description provided	1 (33.3)	1 (25.0)	2 (25.0)	4 (66.7)	11 (52.4)	0 (0.0)	19 (41.3)
No description	2 (66.7)	3 (75.0)	6 (75.0)	2 (33.3)	10 (47.6)	4 (100.0)	27 (58.7)
Total	3 (100.0)	4 (100.0)	8 (100.0)	6 (100.0)	21 (100.0)	4 (100.0)	46 (100.0)

between 1999–2003, 11/25 reports (11 English reports; 0 Japanese reports; 11 in total (44.0%)).

Table 6 shows the methods for assessing QOL in each respective report. Authors used established QOL instruments in 12 reports (11 English reports; 1 Japanese report; 12 in total (26.1%)) and modifications of established instruments in six reports (2 English report; 4 Japanese report; 6 in total (13.0%)). Seven reports (5 English reports; 2 Japanese reports; 7 in total (15.2%)) used non-established QOL instruments but quoted references that described their methodology. Eight reports (3 English reports; 5 Japanese reports; 8 in total (17.5%)) developed original instruments. Except for three QOL scales in which each was used in two reports, a different scale was used in all reports.

Of the remaining articles, 10 reports (9 English reports; 1 Japanese report; 10 in total (21.7%)) assessed only symptoms or performance status, and three reports (2 English report; 1 Japanese report; 3 in total (6.5%)) used methods that were unclear. 30 reports (21 English reports; 9 Japanese reports; 30 in total, 65.2%) specified response rate or number of respondents. Lastly, 35 reports described respondents (26 English reports; 9 Japanese reports; 35 in total (76.1%)).

Discussion

Health status, functional status, and QOL are three concepts often used interchangeably to refer to the same domain of "health." [15] Health-related QOL continues to be used as a measure of outcome in clinical trials [16]. In the present study, we performed a literature search using PubMed in aims of comparing QOL assessment frequencies between international and Japanese RCT reports. Our study, however, has the following limitations. A text-based search was unable to locate articles that do not contain the term, "quality of life," in the abstract, title or as a Medical Subject Headings (MeSH). Also, PubMed does not hold all reports of RCTs published in Japanese [17]. Nonetheless, given that there currently exists no Japanese database of RCT-related articles in Japanese, PubMed serves as the best descriptive database for our study.

While the number of RCT reports referring to QOL published from Japan drastically increased after 1982, this does not necessarily mean that a similar shift exists in relative frequency of total RCTs. The relative frequency of Japanese RCTs rose in parallel with a rising global trend during the 1980s. In the following decade, however, this trend began to diverge from the international one. Although Japanese interest in QOL measures rose in the 1990s [18,19], doubt persisted among clinicians and

Table 6: Type of evaluated measure used in 46 randomized controlled trials reporting on QOL

Measure	Number of trials (%)		
	English Reports	Japanese Reports	Total
Established QOL instruments	11 (34.4)	1 (7.1)	12 (26.1)
Modifications of established QOL instruments	2 (6.3)	4 (28.6)	6 (13.0)
Non-established QOL instruments (references quoted)	5 (15.6)	2 (14.3)	7 (15.2)
Original QOL instrument (non-established)	3 (9.4)	5 (35.7)	8 (17.5)
Symptoms or performance status only	9 (28.1)	1 (7.1)	10 (21.7)
Unclear measure	2 (6.3)	1 (7.1)	3 (6.5)
Total	32 (100.0)	14 (100.0)	46 (100.0)

researchers concerning the validity of subjective measures using interviews and questionnaires [20]. At that time, moreover, little research had focused on the methodologies of QOL assessment. This study's findings, we surmise, reflect this history of QOL in Japan.

Among the 46 reports examined, a total of 10 studies used QOL as a primary endpoint. Previous systematic reviews have criticized researchers for not using a suitable health-related QOL instrument as an outcome measure when studying the effect of intervention [21-25]. Nevertheless, it is still unclear as to whether this reflects a lack an applicable scale or the misuse of available scales [26].

27 of the 46 reports did not describe their reasons for using QOL as an outcome measure. It remains unclear whether this derives from a lack of description concerning outcome measures or insufficient discussion on the need for QOL assessment. It has also been suggested that sponsors and researchers may measure health-related QOL in aims of raising the image of a clinical trial or of the drug under investigation [27]. This study was unable to address this issue because all reports lacked a description of sponsorship and/or conflict of interests. Further studies are needed to investigate and delineate the respective objectives and significance of QOL assessment within each field.

Gill et al. [13] conducted a systematic review of 75 reports published between 1987 and 1991 containing the term QOL in the title and reported that only 15% of reports defined QOL. Our findings show that 32.6% of reports define QOL. Editorial procedures and limited word count, however, may possibly be associated with why QOL measurement selection and its definition were not mentioned. 60.9% of reports used neither an established QOL instrument nor an instrument without modification. This lack of consistency indicates the need for studies to describe their definition of QOL - at least when using their own instrument. Moreover, 50% of studies that used an established instrument did not provide a definition of QOL. This was probably due to the assumption that QOL assessment is equivalent to an establishment scale. This point to the need for defining QOL and for better description as to why an established scale was selected

In the present study, all 15 (32.6%) reports that defined QOL were published after 1993. Furthermore, only four of the 10 reports that used QOL as their primary endpoint actually provided a definition. A total of nine reports (19.6%) that measured symptoms and/or reported the assessment of performance status (PS) in terms of QOL did not clearly define QOL. Only one report published in 1993 used the measure of PS in defining QOL assessment.

While the percentage of reports that assessed symptoms and PS in terms of QOL was 36% (5 out of 14 reports) before the mid-1990s, this percentage dropped to 15.6% (5 out of 32 reports) in later years. In light of this, we surmise that, since 1997, QOL instruments that use a symptom index have slowly been replaced with subjective QOL instruments. That is, QOL instruments that measure subjective QOL have gained acceptance and the concept of QOL has shifted from being objective to subjective.

Clinical researchers can use QOL instruments to measure treatment efficacy, yet questions remain as to how QOL instruments should be selected, used, and how findings should be interpreted [28]. We based our current review on the methods discussed in the reports by Gill et al [13]. and the Scientific Advisory Committee of the Medical Outcomes Trust [14]. This review also took the following items into consideration when examining instrument selection: whether the instrument was disease-specific or comprehensive, whether or not established instruments were tested for validity, whether or not modification of an established instrument was tested for validity, whether or not instruments were tested for validity despite the citation of references, and whether or not instruments were original (developed by the investigators themselves).

Most of reports of this review used different disease-specific scales, and this may be due to the wide range of diseases studied in such a limited sample of RCT reports.

A serious problem apparent in several studies is the use of original instruments that have not been tested for validity or reliability. Garratt [26] has cautioned against this "easy development of new instruments." Previous studies have also indicated the need to consider issues of cultural phenomenon, spirituality [29] and level of medical-service satisfaction in the context of QOL assessment. QOL, being a multifactorial concept, should not be assessed with only one generic instrument [28] or with only one disease-specific instrument, but rather with multiple instruments.

Sanders et al. [9] found that respondents are not clearly described in approximately 30% of RCT reports that use QOL. Our findings intimate the same. The reason may be a lack of interest in the issue of respondents' criteria and/or a mere insufficiency in reporting procedures. Slevin et al. [30] suggests that QOL assessment may have more validity when conducted by the patient him/herself than when conducted by medical providers. We found 18.8% (6 out of 32 articles) of English reports and 35.7% (5 out of 14 articles) of Japanese reports did not describe respondents. Moher et al. [31] further exemplifies that RCT articles written in English provide a clearer description than similar reports written in a non-English language. Our findings show that 34.4% (11 out of 32 articles) of English written reports as opposed to 35.7% (5 out of 14 articles) of Japanese-written reports showed neither response rate nor number of respondents. These insufficiencies in description highlight a need for better reporting standards. Needless to say, a study's quality and validity are most easily assessed by information described in a report [32-34].

Conclusions

Japanese interest in QOL assessment used in RCTs may remain at low levels when compared internationally. Our findings suggest insufficient discussion on when to use QOL as an outcome measure, how to select an appropriate scale and how to accurately use that scale. Further discussion is needed from the standpoints of study objective and psychometrics on the use of QOL assessment as an outcome measure in RCTs and on assessment methodology.

Before doing so, however, it is essential to establish a clear definition of QOL within each field for each particular disease. Contemporary research concerning QOL assessment in RCTs has demonstrated the need for international minimal standards including, but not limited to, scale selection, minimal standards of psychometric validity, and agreed standards of cultural validity [10]. We are confident that by collecting data from nations worldwide, a basis for further discussion on an international framework for QOL will foster. By participating in this discussion, researchers will subsequently gain the tools necessary to improve their nation's domestic handling of QOL assessment.

Authors' contributions

All authors were responsible for planning, conducting and reporting this work and approved the final manuscript.

Additional material

Additional File 1

Table 1 Study of 46 reports. The contents of 46 reports which were assessed in detail

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[http://www.biomedcentral.com/content/supplementary/1477-7525-2-31-S1.doc]

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The Epworth Sleepiness Scaleの性・年齢階級別得点分布と日中の過度の眠気の有症割合の推定

—地域住民を対象とした調査—

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目的　地域住民における主観的な日中の眠気についてThe Epworth Sleepiness Scale（ESS）を用いて測定し，地域住民のESSの分布を記述することである。また，日本における「日中の過度の眠気（excessive daytime sleepiness: EDS）」の有症割合を推定することである。

方法　北海道地方の人口約1万人のある自治体における20歳以上の全住民6,197人を対象とし，2000年10月から12月に自記式質問票を用いた悉皆調査を行った。日本語版ESSを含んだ質問票は自治体の保健推進員の訪問により配布および回収された。解析対象は，ESSの8項目のうち5項目以上を回答したものとした。ESSの合計得点の平均値，標準偏差および性・年齢階級別分布は，分散分析により求めた。EDSの有症割合は，ESSの合計得点11点以上をカットオフ値として推定した。本調査の結果を2000年の性・年齢階級別日本人口を用いて標準化を行い，日本におけるEDSの有症割合を推計した。また，EDSに関連があるとされている諸要因についての検討を行った。

結果　調査票回収数は5,327人（86.0%）であり，解析対象者は4,412人（71.2%）であった。本研究の対象集団におけるESSの平均値（±標準偏差）は5.18±3.75（男性5.25±3.89，女性5.12±3.75）であった。男性，女性ともに年齢階級別のESSの平均値に差がみられた（$P<0.001$）。ESSを用いて推定されたEDSの有症割合は，9.2%（男性9.6%，女性8.8%）であった。2000年の性・年齢階級別日本人口を援用して推計したEDSの有症割合は，9.3%（男性9.6%，女性9.2%）であった。また，EDSは年齢，6時間未満の睡眠，鼾と関連があった（$P=0.002$, $P=0.008$, $P<0.001$）。

結論　地域住民を対象としたESSの性・年齢階級別得点分布と日本におけるEDS有症割合を推定した。これは，日本で初めて推定されたものであり，睡眠障害をきたす種々の疾患の診療，臨床疫学研究および公衆衛生施策に活用されることが期待される。また，ESS得点による日中の眠気が年齢で違いがあることが明らかになった。これについては，生物医学，社会医学的な諸要因が関係していると考えられ，更なる研究が求められる。

Key words：Epworth Sleepiness Scale（ESS），得点分布，日中の過度の眠気（EDS），有症割合，睡眠障害

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I　緒　　言

睡眠障害は，さまざまな心身の疾患の随伴症状として，あるいは罹患率や死亡率における危険因子の一つとして，重要性が近年認識されるようになってきた[1,2]。睡眠障害は，しばしば日中の過剰な眠気（excessive daytime sleepiness: EDS）を引き起こす。EDSは患者の社会生活や交通安

全，公衆衛生上に問題を生じさせることから患者だけでなく社会にとっても対策が必要な重要な症状である[3~7]。また，EDSは睡眠障害の診断および治療結果の評価において重要な指標となっている[8]。EDSは主観的測定方法と客観的測定方法によって評価することができ，ゴールドスタンダードは客観的評価のMSLT（multiple sleep latency test）とされている[9]。MSLTは時間，測定装置および料金の面で非常に浪費が大きい。EDSの主観的評価としてはESS（The Epworth Sleepiness Scale）があり，実施が容易で現在最もよく使われている。ESSは自記式質問票であり，8つの状況下での眠気についてそれぞれ4段階（0～3点）の回答選択肢を有するものである[10]。合計得点が高いほど日中の眠気が強いと評価され，2から10点の範囲が正常であるとされている[11]。このESSは睡眠障害の患者を評価する際に有用であることが報告されている（e.g. narcolepsy syndrome, idiopathic hypersomnolence, obstructive sleep apnea）[12,13]。眠気を評価する際には，その背景にある眠気と関連がある要因の存在を知ることも重要である。既存の研究では，EDSに関連している要因として，短い睡眠時間，鬱，睡眠時の無呼吸や鼾などの睡眠に関係した障害などが明らかになっている。これらの要因を踏まえた上でのESSの標準値は，臨床医や研究者にとって主観的な日中の眠気のスクリーニング，治療効果の評価および疫学研究の比較に有用なものであると考えられる。海外では，患者と健常者の比較はもとより，日中の眠気のハイリスク集団とされている職業集団[13~15]，また地域住民を対象としたESS得点[16]が報告されている。日本でもDoi Yらにより職業集団を対象とした調査が行われている[17]。その調査ではEDS有症割合は，男性が13.3%，女性が7.2%と推定されている。しかし，ESSの得点分布は明示されていない。また，海外では，EDS有症割合はESS以外の方法で推定されたものも多く報告されている[18~23]。日本でもLiu Xらによる地域住民を対象とした研究では，EDSの有症割合は15%と推定されている[24]。しかしながら，この有症割合は日中の眠気を5段階で評価することによって得られたものであり，ESSを用いて推定されたEDSの有症割合と比較することはできないものである。国内外ともにこれまで性・年齢階級別にESSの得点を明示にしているものは皆無であり，ESSを利用する上で情報が不十分であると思われる。ESSは睡眠障害の診療や治療の効果を評価する際によく利用されており，地域住民におけるESSの性・年齢階級別の得点分布を提示することは非常に意義があると思われる。

本研究の目的は，日本の地域住民における主観的な日中の眠気についてESSを用いて測定し，性・年齢階級別得点分布を記述することである。また，日本におけるEDSの有症割合を推計することである。

II 研究方法

1. 調査対象

北海道地方の人口約1万人のある自治体において，2000年8月31日現在の年齢が20歳以上の全住民を対象とした。対象者数は6,197人であった。

2. 調査方法

自記式質問票を用いた悉皆調査を行った。質問票には，日本語版ESSの他，個人属性などの質問項目を含めた。質問票の配布および回収は，2000年10月から12月にかけて自治体の保健推進員による対象者世帯戸別訪問により実施された。調査にあたっては，ID番号，個人名および回答内容が一覧できないような方式を採用し，個人情報保護への配慮を行った。本調査は，財団法人パブリックヘルスリサーチセンターの倫理委員会により承認された。

3. ESSについて

ESSは，最近の日常生活で想定された8つの状況下での眠気を測定するものである。それぞれの質問項目に対する回答方式は4段階の選択肢であり，それぞれの項目の回答に対して0から3の点数が与えられる。ESS得点は8項目の合計得点で，0から24の範囲をとり，得点が高いほど眠気が強いと評価されるものである。ESSは日常の診療の中でよく使用されているが，信頼性および妥当性が検証された日本語版ESSはない。本研究では，英語版ESS[10,25]を改変し，日本語版ESSを作成したものを使用した。

EDSはESSを用いて評価した。ESSの合計得点11点以上をカットオフ値とすると，ナルコレプシーの患者に対する感度は93.5%，特異度は

100%であったと報告されている[26]。また，この値は日本の研究でもEDSの評価に使用されている[17,27]。これらのことより，本研究ではESS合計得点が11点以上であれば，日中の眠気のために日常生活に何らかの障害があると判断し，EDSであると評価した。

4. 解析方法

対象者の属性を把握するために，質問票調査で得られた性別，年齢，平均睡眠時間，睡眠薬の使用の頻度，肥満度および鼾について記述した。

本調査で使用した日本語版ESSに関する計量心理学的な検討として，項目分析，構成概念妥当性（因子分析による因子的妥当性，各項目と合計得点の相関係数による収束的妥当性）およびクロンバックαによる信頼性の検討を行った。

ESSは8つの項目すべてに回答していないと合計得点が算出されないため，1項目でも欠側があった場合はその他の項目の得点が生かされない。そのため，5項目以上回答が得られた場合については，他の回答項目の平均値を用いた補正を行った。回答が3項目以下の場合は，解析対象から除外した。地域住民におけるESSの得点分布を明らかにするために，ESSの度数分布と性・年齢階級別のESS合計得点の平均値を求めた。年齢は，10歳ごとにカテゴリー化した。従属変数をESS合計得点，説明変数を年齢階級として，分散分析を行った。このとき，Bonferroni法により多重比較を行った。また，男女別に同様の解析を行った。欠側を補正したことによる影響をみるために，全項目回答者と欠側補正対象者のESS合計得点についてt検定を行った。また，全項目回答者と欠側補正対象者の属性を比較するために，性別および年齢階級についてχ^2検定を行った。

次いで，日本人のEDSの有症割合を推定するために，ESSの合計得点11点以上をカットオフ値として本研究の対象集団における性・年齢階級別EDSの有症割合を求めた。EDS有症割合が性別，年齢階級において差があるかを明らかにするためにχ^2検定を行った。また，EDSの有無を従属変数，性，年齢に加え，EDSとの関連が示されている睡眠時間の不足（6時間未満の睡眠），BMI，鼾を説明変数としたロジスティック回帰分析を行った。

EDSの評価におけるESSのカットオフ値の設定は研究者により様々であり，はっきりとは確定されてはいないことから，カットオフ値を9から12の範囲に変化させてEDS有症割合を推定した。また，本研究の対象集団の性・年齢階級別のEDS有症割合と2000年の性・年齢階級別日本人口（国勢調査）[28]から，直接法により標準化を行い，日本におけるEDS有症割合を推計した。

統計解析には，SPSS 11.0J for Windows（SPSS Inc., 2001）を用いた。

Ⅲ 結　　果

調査票配布数は対象者条件該当者6,197人のうち転出，死亡を除いた6,116人（98.7%）であり，回収数は5,327人（86.0%）であった。ESSの各項目の有効回答数は4,124～4,624人（66.5%～74.6%）であり，全項目すべてに回答し合計得点が得られたものは3,893人（62.8%）であった。欠側補正対象者を含めた解析対象者数は4,412人（71.2%）であった。

1. 対象者属性

回答者数は，男性が2,025名，女性が2,387人であった。平均年齢は男性が52.0歳，女性が52.1歳であった。BMIの平均は男性が23.6（kg/m²），女性が22.9であった。過去1か月間の平均睡眠時間は男性が7.3時間，女性が7.0時間であり，男性の5.9%および女性の8.7%が1週間に1回以上睡眠薬を使用していた。また，鼾については男性の29.6%，女性の12.4%が「毎晩かく」あるいは「よくかく」と回答した（表1）。

2. ESSについて

未回収者を除いた5,107人のうち，全項目に回

表1　対象者の属性

	男性（n=2,025）		女性（n=2,387）	
	n		n	
年齢	2,025	52.0±16.7	2,387	52.1±17.1
BMI	1,947	23.6±3.7	2,207	22.9±3.6
睡眠時間（過去1か月間）	1,968	7.3±1.2	2,313	7.0±1.2
睡眠薬使用（1週間に1回以上）	1,983	118(5.9)	2,327	203(8.7)
鼾（毎晩，よくかく）	1,990	589(29.6)	2,357	292(12.4)

注）年齢，BMI，睡眠時間：平均値±標準偏差
睡眠薬使用，鼾の頻度：度数（%）