

III. 研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書籍名	出版社名	出版地	出版年	ページ
明智龍男, 内富庸介	がん患者の抑うつ症状緩和-最近の話題	樋口輝彦	別冊・医学のあゆみ 最新-うつ病のすべて	医師薬出版株式会社	東京	2010	160-164
明智龍男	せん妄なのか、アカシジアなのか分からない時の対応	森田達也, 新城拓也, 林めぐり子	緩和ケアのちよつとしたコツ	青海社	東京	2010	238-240
明智龍男	希死念慮・自殺	大西秀樹	専門医のための精神科臨床リュミエール24 サイコロジョロジー	中山書店	東京	2010	69-74
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明智龍男	かかりつけ医が理解すべきがん患者のこころの変化-診断から終末期まで	池田健一郎	患者・家族の相談に応えるがん診療サポートガイド	南山堂	東京	2011	777-781
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明智龍男	がん治療における精神的ケアと薬物療法	古瀬純司	消化器がん化学療法ハンドブック	中外医学社	東京	2011	83-90
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明智龍男	希死念慮	清水研	がん診療に携わるすべての医師のための心のケアガイド	真興交易(株) 医学出版部	東京	2011	62-65
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明智龍男	心理社会的介入	内富庸介, 小川朝生	精神腫瘍学	医学書院	東京	2011	194-201
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IV. 研究成果の刊行物・別刷り



CGAを考慮した高齢者に対するがん治療の特性と適応

高齢者のがんに対する 総合的機能評価*

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Key Words : geriatric assessment, older cancer patients, CSGA, VES-13

はじめに

悪性新生物は高齢者に多いことが知られており、超高齢社会を迎えたわが国では、がん薬物療法を受ける高齢者数は増加している。高齢者における薬理学的特徴は、薬物吸収の低下、分布用量の変動、肝代謝能の低下、腎排泄能の低下といった医学的視点で捉えることができる。高齢者におけるこのような変化を勘案して、適切な薬物治療を選択する必要があるが、レジメン選択から用量調節にいたるまで判断に迷うことも少なくない。多くの臨床試験では、暦年齢に加えて、performance status (PS) や臓器機能により、適格基準を設けている。合併症の存在はPS評価を困難にするため、PSは若年患者と比較して高齢患者では信頼性がないと考えられている¹⁾。一般的に担当医は、高齢患者の全身状態に影響する因子を完全には評価していないことが多いことも報告されている²⁾。年齢、PS、合併症以外の新たな指標を用いることで、最適な治療方針を決定するための診療支援につながる可能

性がある。加齢に伴う機能変化以外にも社会的・精神心理的な状況に配慮した総合的な評価に基づいて、診療を行う考え方である。

高齢者総合的機能評価

総合的機能評価とは、「疾患の評価に加え、日常生活機能評価として日常生活活動度 (activity of daily life ; ADL), 手段的日常生活活動度 (instrumental ADL ; IADL), 認知能, 気分・情緒・幸福度, 社会的要素・家庭環境などを、確立した一定の評価手技にのっとり測定・評価すること」とされる³⁾。高齢者は、複数の疾患を抱え、慢性疾患に罹りやすく、病前の状態に復帰するのが困難、疾患により quality of life (QOL) が損われるなどの特徴があるため、全体像を把握し、疾患の治療と並行してQOLの維持を図るとともに、QOLの悪化を予防する必要がある。この全体像を把握するために、高齢者総合的機能評価 (comprehensive geriatric assessment ; CGA) が行われ、1) ADL, 2) IADL, 3) 認知能, 4) 情緒・気分・幸福度, 5) コミュニケーション, 6) 社会的環境 (家庭環境, 介護者, 支援体制など) を基本的構成成分としている⁴⁾。在宅診療・介護・リハビリなどの治療方針に役立つとされ、老年医

* Geriatric assessment in older cancer patients.

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学の領域では多くの検討が行われてきた。

1. がん診療におけるCGAの位置づけ

NCCNガイドライン (Senior Adult Oncology) によれば、加齢は個人差が大きいため、がん治療が適切かの判断は、余命の推定やリスクの評価が重要であるとされている。これまでにがん診療においてもCGAの有用性が報告されており^{9)~7)}、International Society of Geriatric Oncology (SIOG) は、がん診療におけるCGAの実施を推奨している。2013年のSIOG学術集会において「高齢がん患者の高齢者機能評価に関するSIOGコンセンサス」がアップデートされた。CGAを行う理由(質問1)として、以下の3つがあげられている。①未確認の問題およびリスクの発見、②有害転帰の予測(たとえば、有害事象、機能あるいは認知力の低下、術後合併症など)、③余命予測および悪性腫瘍による死亡の予測の補助である。

非小細胞肺癌を対象として、年齢とPSで化学療法適応を判断する群(コントロール群)とCGAを実施して虚弱を評価し化学療法適応を判断する群(CGA群)の第III相比較試験が行われ、フランスのグループから結果の一部が公表された。CGA群で有害事象は有意に少なかったが、主要評価項目である治療成功期間(time to treatment failure)については2群間で有意な差はみられなかった。CGA群では対症療法となった対象が21%存在しており、化学療法の適応とならない虚弱な対象を適切に除外できる可能性があり、興味深い⁹⁾。

2. 研究の視点

今後の必要な研究の視点として、①臨床研究に加齢に関連するバイオマーカーや機能評価を組み込む、②75歳以上の高齢者とハイリスク高齢者を臨床研究に多く組み入れる、③腫瘍学と老年医学などの多部門間の連携やICTを活用したインフラ整備の重要性などが米国の研究者から指摘されている⁹⁾。本邦でも、機能評価を取り込んだ臨床研究は少なく、コントロールデータも整備されておらず、米国と同様に解決すべき課題は多い。

厚生労働省がん臨床研究事業 におけるCGA研究の概要

がん患者における高齢者総合的機能評価の確立をめざして、2011年度からがん臨床研究事業として検討を行ってきたので、本邦における取り組みの一部として紹介したい。

1. CSGA日本語版およびデータ採録システムの開発

CGAをがん患者用に特化させたcancer-specific geriatric assessment (CSGA)の日本語版を、原作者(米国のDr. Hurria)と協議しながら開発した。CSGAは、背景情報と7つの下位項目から構成され、具体的には、身体機能(ADL, IADL, KPS, timed up and go, 転倒回数)、内服薬、合併症、抑うつの評価、社会機能、社会的支援、栄養状態である¹⁰⁾。これらの質問項目は、すでに老年医学で検討されてきた一般的なCGAと関連付けられており、日本をはじめ世界で検討されている質問項目が含まれている。日本語版作成にあたっては、介護保険に関する項目を追加し、他の尺度の日本語訳を参考にして作成した。

米国ではCSGAを用いてリスク因子を抽出し〔年齢(72歳以上)、がん腫(消化器または泌尿器)、化学療法開始用量が標準量かどうか、多剤併用かどうか、ヘモグロビン低下(男性<11 g/dl; 女性<10 g/dl)、クレアチニンクリアランス低下、過去6か月以内の転倒回数(1回以上)、聴覚障害、1ブロックの歩行不能、服薬に助けを必要とする、社会的活動の減少の11項目)〕、がん薬物療法における重篤な有害事象を予測するモデルが提唱されている¹¹⁾。現在このモデルの検証中である。CSGA日本語版の実施には時間・労力の点からタブレット端末を用いた採録が効率的と考え¹²⁾、日本臨床腫瘍研究グループ(JCOG)と協力して、web上でデータのやり取りが可能な採録システムを構築した。今後の臨床研究において活用を進めていく。

2. 高齢者を対象とした多施設臨床試験におけるVES-13の検討

75歳以上および70~74歳の虚弱高齢者における治癒切除不能な進行/再発大腸がん患者を対象に、標準治療群であるフルオロピリミジン(5-FU/LV

またはカペシタビン)+BEV(ベバシズマブ)療法に対する、試験治療群のフルオロピリミジン+オキサリプラチン(mFOLFOX7, またはCapeOX)+BEV療法の無増悪生存期間(progression-free survival; PFS)における優越性をランダム化比較第III相試験において検証する試験(JCOG1018)が進行中である。主要評価項目は無増悪生存期間(A群 vs. B群), 副次的評価項目は全生存期間(A群 vs. B群), 奏効割合, 有害事象発生割合, QOL(EQ-5D)である。この試験において, 高齢者機能評価のスクリーニングツールであるVulnerable Elders Survey-13(VES-13)を用いた付随研究を実施している。

VES-13は, Salibaらが開発した13項目の自己報告ツール¹³⁾で, コミュニティに居住する高齢者の機能低下のリスクを評価するためRAND Corporationを通して承認されている。この簡便なスクリーニングツールは, ACOVEプロジェクト(Assessing Care of Vulnerable Elders)の一環として, 脆弱高齢者集団を定義し, 診療の質の指標を設定するために利用可能であることが示されている¹⁴⁾。VES-13は, CGAと同様またはさらに広範に実施可能であることが示されており, CGAの異常を検知する感度は72.7%, 特異度85.7%であり¹⁵⁾, コミュニティに居住する高齢者¹³⁾¹⁴⁾およびがん患者¹⁵⁾¹⁶⁾において検証されている。記入まで平均5分以下である¹⁷⁾。本邦では, 明智らが日本語版を開発し, 検証を行っている(厚生労働省がん臨床研究事業)。

3. 急性期病院(高齢医学科)入院がん高齢患者の現状—治療法選択とCGA

虚弱高齢者のがん治療に関する治療指針はない。入院したがん患者を対象に後ろ向きにカルテを調査し, 治療方針決定にかかわる要素を抽出し, CGAとの関係を検討した。2009年1月から2012年10月までに杏林大学高齢医学科入院となった患者1,363名中担がん患者89名を対象に, ①入院時主病名, ②がん種, ③治療法の選択, ④CGA7と治療法選択の関係, ⑤JABCランクと治療法選択の関係, ⑥治療法決定因子, ⑦入院前の居住場所と退院先・転帰について調査した。有意差はみられなかったものの, 積極的治療を選んだ群でCGA7の得点が高い傾向にあった。治

療方針の決定について, 前立腺がん患者の約2/3が患者自身の意志で治療方針を選択しているが, その他のがん患者では本人の意志が確認されたのは3割以下で, 半数以上は家族が治療方針を決定していた。自宅復帰率は積極的治療群では前立腺がん患者で60%, その他のがん患者では20%と当科の一般入院患者の自宅復帰率65%に比べ, 著明に低かった。がん治療に対する本人・家族の意見では「高齢なので本人に負担のかかる(つらい)治療は望まなかった」, あるいは「今回の治療は常々本人が望んでいた方針である」というのが, 最も多く寄せられた意見であった。家族だけで治療方針を決めた症例でも常々本人が望んでいた治療方針であることを汲み取り, 家族が意志決定を行っていた症例もみられた。

4. 高齢がん患者における診療の質指標(QI)の測定

がん診療の質指標(quality indicator; QI)を利用し, 患者年代ごとにQIスコアを算出することで, 高齢者のがん診療実態を検討した。がん診療連携拠点病院7施設において, 2010年に治療を受けた5大がん(胃がん, 大腸がん, 乳がん, 肺がん, 肝がん)患者を対象とした。患者情報を院内がん登録から収集し, DPC(E/Fファイル)から診療行為を収集できるように, 各施設で共通の匿名IDで両者を連結可能にしたものを使用した。この方法で計算可能な10個のQIを測定した。4,785人(65歳未満2,103人, 65~74歳1,363人, 75~79歳646人, 80~84歳448人, 85歳以上225人)が対象で, 術後の補助療法に関するQI(胃がんに対する術後化学療法, 大腸がんに対する術後化学療法, 乳房温存術後の放射線療法, 乳房切除後の高リスク乳がんに対する放射線療法)は, 年代が上昇するごとに実施率は低下していった。制吐剤の使用など有害事象予防のQIに関しては, 年代が上昇しても実施率は変化がなく, 高齢がん患者に対して診療の質の改善余地の可能性が示唆された。

おわりに

高齢者のがん治療を包括的に検討し, 標準化の可能性や社会全体における治療体系の整合性を考慮することは重要である。ただし, 本邦に

おけるこの分野の研究は緒に就いたばかりである。JCOGでは、研究者間の情報共有、geriatric assessment toolの標準化、臨床試験に登録されない患者データの取り扱いなど、高齢者研究を推進するための準備を進めている。複数分野の研究者の協働を含め、わが国に最適化した研究展開が必要で、10年先を見据えた研究体制の構築が望まれる。

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Impaired mental health among the bereaved spouses of cancer patients

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Abstract

Objective: Few cancer physicians routinely provide bereavement follow-up in clinical practice. The purpose of this study was to identify the prevalence of impaired mental health among the bereaved spouses over several years and explore the indicators for early detection of high-risk spouses during end-of life (EOL) care.

Methods: A cross-sectional mail survey was conducted for the bereaved spouses of patients who had died at the National Cancer Center Hospital of Japan. Bereaved spouses with potential psychiatric disorders were identified by the cut-off score of the 28-item General Health Questionnaire. Associated factors of potential psychiatric disorders were explored by logistic regression analysis.

Results: A total of 821 spouses experiencing bereavement from 7 months to 7 years returned the questionnaires. Overall mean prevalence of potential psychiatric disorders was 44% (360/821). Bereaved spouses 'under 55 years' (71%) or '2 years after bereavement' (59%) revealed a significantly higher prevalence ($p < 0.01$). Associated factors during EOL care were several characteristics such as 'spouses' history of psychiatric disorder (odds ratio (OR) = 3.19), 'patients' with stomach cancer (OR = 1.87), and 'patients' using psychiatric consultation services (OR = 1.52) as well as spouses' dissatisfaction with EOL care such as 'physicians' treatment of physical symptoms' (OR = 3.44) and 'time spent communicating with patients' (OR = 1.55).

Conclusions: Nearly half the bereaved spouses showed potential psychiatric disorders even 7 years after bereavement. Patients' psychological distress, spouses' history of psychiatric disorder, and dissatisfaction with EOL care were indicators of high-risk spouses.

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Introduction

Conjugal bereavement was the strongest risk factor for depression among elderly community subjects in a meta-analysis of 20 studies (odds ratio (OR) = 3.3) [1] and bereaved spouses showed a significant increase in the risk of depression compared with married people in large cohort studies (1.5-fold, 3.6-fold) [2,3]. In oncology settings, spouses experienced the highest levels of distress among family members at the time of patient death [4] and bereavement brought an increased risk of major depressive disorder [5,6]. Cancer is a leading cause of death worldwide and accounted for 7.6 million deaths (around 13% of all deaths) in 2008 [7]; however, few cancer physicians routinely provide bereavement follow-up in clinical practice [8].

Several longitudinal studies have reported that impaired mental health among the bereaved clearly diminishes over time. The prevalence of major depressive disorder among caregivers of cancer patients was identified by clinical interview: 28% at the time of hospice enrollment, 12% at 6 months after death, and 7% at 1 year after death [5,6]. Depression, anxiety, and grief measured by self-administered questionnaire decreased during the first year after bereavement [9–11] and then remained unchanged over the next year [11]. On the other hand, cross-sectional studies reported that negative effects such as anger, sadness, self-blame, and guilt did not decrease among those who had been bereaved for more than 4 years [12,13] and 25% of the bereaved parents had not worked through their grief even 4–9 years after the loss [14]. However,

these persistent symptoms could not predict the prevalence of potential psychiatric disorders among the bereaved.

Impaired mental health among the bereaved who have lost a relative to cancer is associated with several characteristics of the patients and the bereaved. As for clinical characteristics of cancer patients, 'short duration of hospice enrollment' [5,6], 'intensive end-of-life (EOL) care' [15], and 'ICU death' [16] were associated with impaired mental health among the bereaved. In addition, bereaved characteristics of 'under 65 years' [9], 'female' [5,17,18], 'spouse' [5], 'prior physical symptoms' [5], 'prior depression' [5,9,17], and 'anticipatory grief' [16] were also reported. However, these associated factors are not useful as indicators for early detection of high-risk spouses during EOL care in clinical practice at a hospital even though 90% of cancer patients in Japan die in a hospital [19].

In the present study, the primary purpose was to identify the prevalence of impaired mental health that can be used to predict the prevalence of potential psychiatric disorders among the bereaved who have lost their spouse to cancer. The secondary purpose was to investigate associated factors of the prevalence so that we could suggest the indicators for early detection of high-risk spouses during EOL care.

Methods

Study sample

We conducted a cross-sectional mail survey for the bereaved spouses whose partner had died at the National Cancer Center Hospital East (NCCHE). This study was

approved by the Institutional Review Board and Ethics Committee of the National Cancer Center of Japan in January 2009.

First, in January 2009, we found it necessary to identify family members to whom we intended to mail study participation invitations; this was because of a lack of accurate data about marital status in the hospital patient database. Eligibility criteria were (i) patient's primary clinician belonging to the eight divisions cooperating with this study (Hematology, Pancreatic, Head and Neck, Gastric Surgery, Gastrointestinal, Thoracic Surgery, Thoracic Oncology, and Palliative Care), which covered 98% of the patients who died at NCCHE; (ii) patient's data available in the hospital's patient database operating since January 2001; and (iii) patient's death occurring at least 6 months earlier. Exclusion criteria and flow of the study sample are explained in Figure 1.

We matched the demographic characteristics of the deceased cancer patients drawn from the hospital patient database with those of the bereaved spouses based on the completed questionnaires. Respondents' characteristics ($n=821$) showed a lower proportion of males (30%, $n=242$ vs. 36%, $n=753$, $p < 0.01$) and a shorter duration of bereavement (3.0 ± 1.9 vs. 3.2 ± 2.0 years, $p < 0.01$) compared with the non-responders ($n=2081$) among the 2902 candidate participants; the difference in values of the deceased patients' characteristics such as age, duration of last hospital admission, place of death, history of usage of psychiatric consultation services, and cancer site was not significant.

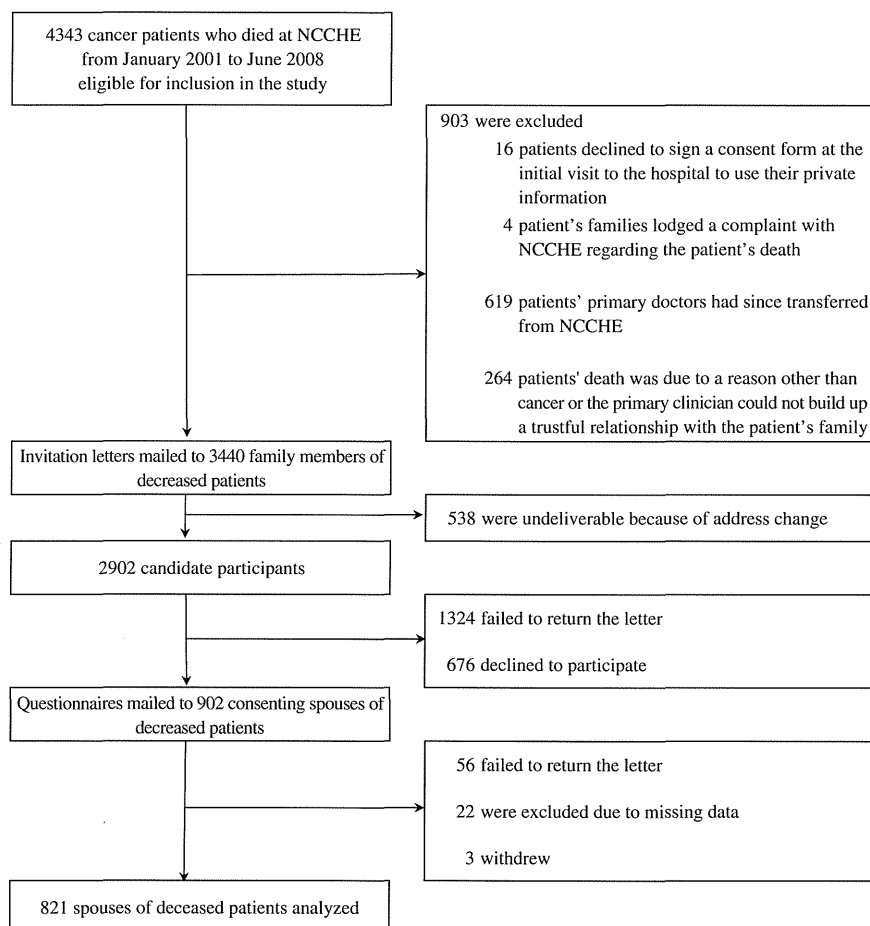


Figure 1. Flow of study sample

Measures

Deceased patients' characteristics

We examined the overall computerized patient database of NCCHE to identify cancer patients' characteristics. Time since cancer diagnosis to death was declared in the questionnaires completed by the bereaved. History of usage of psychiatric consultation services was identified by using the consultation database developed by the Psychiatric Services Division of the NCCHE. This computerized database [20] includes demographic variables and psychiatric disorders of patients who were referred to the Psychiatric Services Division.

Bereaved spouses' characteristics

The questionnaires completed by the bereaved spouses included physical and psychological information such as physical illness under treatment and history of psychiatric disorder prior to their partner's death as well as demographic variables.

Dissatisfaction with EOL care

The bereaved spouses retrospectively reported their dissatisfaction with EOL caregiving (five items) and physician's EOL care (four items) during the month prior to the patient's death using a five-point Likert-type scale (0: very satisfied, 1: fairly satisfied, 2: neutral, 3: fairly dissatisfied, 4: very dissatisfied). We rescored each item as 0 (absence of dissatisfaction, 0–2) or 1 (presence of dissatisfaction, 3–4) in this study.

Impaired mental health

The General Health Questionnaire (GHQ), using a four-point Likert-type scale (possible range, 0–3; higher scores indicate impaired mental health), has been widely used to detect persons with nonspecific psychiatric disorders [21]. We used the validated Japanese 28-item version (GHQ28 [22]). Persons with potential psychiatric disorders were identified by the cut-off score of the GHQ scoring method (0–0.1–1; possible range, 0–28; cut-off score, 5/6). This cut-off score showed the best sensitivity and specificity when compared with the ratings of the clinical interview [23,24] and this approach has shown its applicability to the Japanese version [22].

Statistical analysis

Impaired mental health was compared using analysis of variance with the Bonferroni multiple comparison method or *t*-test. Potential psychiatric disorders were compared by using the chi-square test with residual analysis. Variables showing *p*-values < 0.05 in the univariate analysis were entered as independent variables in a multivariate logistic regression analysis with backward elimination to identify associated factors of potential psychiatric disorders.

P-values < 0.05 were considered significant and all *p*-values were two-tailed. All statistical analyses were carried out using SPSS ver.12.0J for Windows (SPSS Japan Institute Inc., Tokyo, Japan).

Results

Characteristics of deceased patients/bereaved spouses

Table 1 summarizes the characteristics of the 821 participants experiencing bereavement from 7 months to 7 years.

Table 1. Characteristics of deceased patients and bereaved spouses (*n* = 821)

	Mean ± SD (median, range)	<i>n</i> (%)
Deceased patients' characteristics		
Age, years	64 ± 9.0 (65, 32–88)	
Time since cancer diagnosis to death, months	27 ± 29 (16, 1–187)	
Duration of last hospital admission, days	27 ± 29 (17, 1–208)	
Bereaved spouses' characteristics		
Age, years	66 ± 9.0 (66, 32–89)	
Time since bereavement, years	3.0 ± 1.9 (3.0, 0.6–7.2)	
Gender		
Male		242 30
Female		579 70

SD, standard deviation.

In this study, 579 bereaved (70%) were female, 441 patients (54%) died in the Palliative Care Unit, and 629 bereaved (77%) were involved in EOL caregiving 'everyday'.

Prevalence of impaired mental health and potential psychiatric disorders

As shown in Table 2, we estimated the population of bereaved spouses to be 2649 by multiplying the total number of 4343 deceased patients by 0.61, which is the approximate ratio of Japanese cancer patients who have a spouse at the time of death among overall cancer deaths in Japan in 2007 (206,389/336,139)[19]. As a result, the overall sampling rate (estimated) was 31% (821/2,649), and the prevalence of potential psychiatric disorders was 44% (360/821, 95% CI = 40.6–47.4).

With impaired mental health, three-way interaction (age × gender × time) was not significant ($F(18, 689) = 1.56, p = 0.07$). Two-way interaction (age × gender: $F(3, 689) = 2.75, p = 0.04$) was significant: males 'under 55 years' showed significantly greater prevalence than males '55–64 years' or 'over 75 years' ($F(3, 214) = 3.66, p = 0.01, A_0 > A_1, A_3, p < 0.05$) and females 'under 55 years' or '55–64 years' showed significantly greater prevalence than females '65–74 years' ($F(3, 533) = 4.65, p < 0.01, A_0, A_1 > A_2, p < 0.05$). The main effect of time was significant ($F(6, 689) = 2.71, p = 0.01$): the bereaved who had lost their spouse '2 years ago' revealed significantly greater prevalence than those who had lost their spouse '4 years ago' with multiple comparison ($F(2, 738) = 3.31, p < 0.01, T_2 > T_4, p < 0.05$).

The prevalence of the bereaved varied with age and time: 'under 55 years' (71%) revealed significantly higher prevalence than those '65–74 years' (42%) ($\chi^2(3) = 23.17, p < 0.01, A_0 > A_2, p < 0.01$) and the bereaved who had lost their spouse '2 years ago' (59%) revealed significantly higher prevalence than those who had lost their spouse '4 years ago' (37%) ($\chi^2(6) = 17.81, p < 0.01, T_2 > T_4, p < 0.01$). No significant difference was observed between genders ($\chi^2(1) = 1.08, p = 0.34$).

Factors associated with potential psychiatric disorders

In the univariate analysis, 14 variables were significantly associated with potential psychiatric disorders ($p < 0.05$, Table 3). Table 4 shows the results of a multivariate logistic regression analysis: 'patients using psychiatric consultation

Table 2. Prevalence of impaired mental health and potential psychiatric disorders among bereaved spouses of cancer patients

	Year	Group	Deceased patients	Population ^a (estimated)	Sample	Sample rate (estimated)	Impaired mental health (GHQ28, 0–28)		Potential psychiatric disorders (GHQ28 ≥ 6)	
			N	N'	n	% (n/N')	Mean (SD)	n'	% (n'/n)	95% CI
Total			4343	2649	821	31	7.17 (6.79)	360	44	40.6–47.4
Age										
	–54	A0			75		(9.95) 6.59	53	71	60.4–81.0
	55–64	A1			232		7.65 (6.77)	118	51	44.5–57.3
	65–74	A2			339		6.37 (6.68)	141	42	36.4–46.9
	75–	A3			109		6.62 (6.77)	46	42	32.9–51.5
Gender										
	Male		1494	911	220	24	6.93 (6.65)	98	45	37.9–51.1
	Female		2849	1738	538	31	7.27 (6.86)	262	49	44.5–52.9
Time since bereavement										
	<1	T0	258	157	55	35	8.67 (7.41)	30	55	41.3–67.7
	<2	T1	668	407	133	33	7.79 (7.38)	66	50	41.1–58.1
	<3	T2	611	373	134	36	8.60 (6.92)	79	59	50.7–67.3
	<4	T3	616	376	111	30	6.00 (6.29)	44	40	30.5–48.7
	<5	T4	643	392	96	24	5.48 (6.05)	35	37	26.9–46.1
	<6	T5	671	409	108	26	6.74 (6.56)	45	42	32.4–51.0
	≥6	T6	876	534	108	20	6.97 (6.55)	55	51	41.5–60.3

Some percentages do not add up to 100% because of missing data.

SD, standard deviation; CI, confidence interval.

^aPopulation was estimated by multiplying the number of deceased patients (N) by 0.61, which is the approximate ratio of Japanese cancer patients who have a spouse at the time of death among overall cancer deaths in Japan in 2007.

services' (OR = 1.52), 'patients with stomach cancer' (OR = 1.87), and 'bereaved with a history of psychiatric disorder' (OR = 3.19) were significantly associated factors among the characteristics of patients/bereaved prior to the patient's death. Additionally, 'time spent communicating with patients' (OR = 1.55) and 'physician's treatment of physical symptoms' (OR = 3.44) were significantly associated factors among the bereaved spouses' dissatisfaction with EOL care during the final month.

Discussion

In this study, we identified a considerably high prevalence of potential psychiatric disorders among the bereaved (44% of total respondents). Patients' psychological distress, bereaved spouses' history of psychiatric disorder, and dissatisfaction with EOL care were indicators for early detection of high-risk spouses prior to the patient's death.

Our results indicated that, even 7 years after losing their spouse, a significant number of the bereaved have potential psychiatric disorders (37–59%). This is a higher prevalence than that of consecutive patients in general practice in Britain (35%) [25] and is three-fold higher than that of a healthy sample in Japan (14%) [22]. We discuss this high prevalence from two aspects of the results. First, more than half the spouses within less than 3 years since bereavement showed potential psychiatric disorders. This high prevalence might be inflated by normal grief, a common psychological reaction among the bereaved. Our results support those of the previous studies in which prevalence decreased during the first year after bereavement [9–11]. However, our results do not support previous results where prevalence remained unchanged over the second year [11]. This discrepancy might partly be because of spouses participating in the Japanese Buddhist rite of *sankaiki* where bereaved families gather together on the second anniversary of the death and reminisce about the deceased. This mourning ceremony might increase

the psychological distress of the bereaved by triggering negative psychological states such as yearning, an unfulfilled desire to reunite with the deceased. Second, around 40% of the respondents whose bereavement was 3–7 years earlier showed potential psychiatric disorders. Even though their psychological distress might have eased somewhat after the mourning ceremony in the second year, the prevalence of both impaired mental health and potential psychiatric disorders was considerably high among the spouses after bereavement. This result could be because of subsequent physical problems of the bereaved because 'physical illness under treatment' was significantly associated with morbidity. However, this persistent prevalence might suggest prolonged bereavement distress because dissatisfaction with EOL (their caregiving and the physician's care) was strongly associated with potential psychiatric disorders in this study.

Among the characteristics of patients/bereaved, 'bereaved spouse's history of psychiatric disorders prior to the patient's death' was the most highly correlated factor (OR = 3.19) and replicated previous studies on the indicators of vulnerability to bereavement stress [5,9,17]. Patients with stomach cancer in this study might have a higher rate of psychological symptoms because the highest rate of mixed anxiety/depression symptoms (20%) was seen with stomach cancer patients among 22 cancer types in a large cohort study [26]. Considering the positive association between patient and caregiver psychological distress in meta-analyses [27,28], patients' psychological distress factors of 'stomach cancer' or 'usage of psychiatric consultation service' could raise spouses' psychological distress prior to the patient's death. In addition, because psychological distress of caregivers prior to the patient's death predicted its prevalence after bereavement in a longitudinal multisite study [16], the initial detection of spouses with high psychological distress prior to the patient's death might be the most useful strategy for preventing subsequent impaired mental health among the bereaved.

Table 3. Factors associated with potential psychiatric disorders among bereaved spouses of cancer patients: univariate analysis

Variables	Potential psychiatric disorders						Analysis	
	Total		Presence		Absence		χ^2	p
	n	(%)	n	(%)	n	(%)		
Deceased patients' characteristics								
Age (< 65 years)	386	(47.0)	198	(51.3)	188	(48.7)	4.56	0.04
Time since cancer diagnosis to death (< 1 year)	285	(34.7)	144	(50.5)	141	(49.5)	1.69	0.20
Duration of last hospital admission (< 1 week)	182	(22.2)	93	(51.1)	89	(48.9)	1.25	0.27
Place of death (Palliative care unit)	402	(49.0)	190	(47.3)	212	(52.7)	0.02	0.94
History of usage of psychiatric consultation service	152	(18.5)	87	(57.2)	65	(42.8)	7.24	<0.01
Cancer site								
Lung	241	(29.4)	113	(46.9)	128	(53.1)	0.05	0.88
Pancreas	88	(10.7)	39	(44.3)	49	(55.7)	0.40	0.57
Stomach	60	(7.3)	38	(63.3)	22	(36.7)	6.56	0.02
Colon	63	(7.7)	24	(38.1)	39	(61.9)	2.42	0.15
Head and neck	60	(7.3)	25	(41.7)	35	(58.3)	0.89	0.42
Esophagus	45	(5.5)	26	(57.8)	19	(42.2)	2.03	0.17
Breast	41	(5.0)	20	(48.8)	21	(51.2)	0.03	0.87
Liver	38	(4.6)	17	(44.7)	21	(55.3)	0.12	0.74
Biliary tract	33	(4.0)	19	(57.6)	14	(42.4)	1.41	0.29
Lymphoma	9	(1.1)	4	(44.4)	5	(55.6)	0.03	1.00
Bereaved spouses' characteristics								
Age (< 65 years)	307	(37.4)	171	(55.7)	136	(44.3)	13.94	<0.01
Gender (Male)	220	(26.8)	98	(44.5)	122	(55.5)	1.08	0.34
Time since bereavement (< 3 years)	322	(39.2)	175	(54.3)	147	(45.7)	10.55	<0.01
Living status (Living alone)	363	(44.2)	171	(47.1)	192	(52.9)	0.04	0.88
Employment status (Employed)	216	(26.3)	106	(49.1)	110	(50.9)	0.30	0.63
Education (≤ 9 years)	121	(14.7)	51	(42.1)	70	(57.9)	1.65	0.23
Physical illness under treatment	424	(51.6)	227	(53.5)	197	(46.5)	14.10	<0.01
History of any psychiatric disorder prior to patients' death	60	(7.3)	43	(71.7)	17	(28.3)	15.37	<0.01
Bereavement experience after the death of spouse	196	(23.9)	91	(46.4)	105	(53.6)	0.12	0.74
Religiousness	311	(37.9)	157	(50.5)	154	(49.5)	1.89	0.18
Involvement in end-of-life caregiving (Everyday)	579	(70.5)	285	(49.2)	294	(50.8)	2.94	0.09
Dissatisfaction with end-of-life caregiving								
Knowledge of physical symptoms and management	235	(28.6)	130	(55.3)	105	(44.7)	9.01	<0.01
Professional supports for physical symptoms and management	177	(21.6)	104	(58.8)	73	(41.2)	12.31	<0.01
Knowledge of psychological symptoms and management	228	(27.8)	119	(52.2)	109	(47.8)	3.20	0.08
Professional supports for psychological symptoms and management	208	(25.3)	122	(58.7)	86	(41.3)	14.99	<0.01
Time spent communicating with patients	169	(20.6)	99	(58.6)	70	(41.4)	10.93	<0.01
Dissatisfaction with physicians' end-of-life care								
Treatment of physical symptoms	67	(8.2)	49	(73.1)	18	(26.9)	19.44	<0.01
Treatment of psychological symptoms	119	(14.5)	71	(59.7)	48	(40.3)	8.66	<0.01
Time spent communicating with patients	191	(23.3)	104	(54.5)	87	(45.5)	5.21	<0.01
Time spent communicating with patients' families	232	(28.3)	123	(53.0)	109	(47.0)	4.17	0.05

Fisher's exact test was performed when the sample number was less than 10. All variables were coded as: 0 = absence, 1 = presence.

Table 4. Factors associated with potential psychiatric disorders among bereaved spouses of cancer patients: multivariate logistic regression analysis

Variables	Beta	SE	OR	95% CI	p
Deceased patients' characteristics					
History of usage of psychiatric consultation service	0.42	0.20	1.52	1.02–2.26	0.04
Stomach cancer	0.63	0.30	1.87	1.04–3.38	0.04
Bereaved spouses' characteristics					
Age (< 65 years)	0.72	0.17	2.06	1.47–2.88	<0.01
Time since bereavement (< 3 years)	0.46	0.16	1.58	1.15–2.17	<0.01
Physical illness under treatment	0.82	0.17	2.26	1.62–3.16	<0.01
History of any psychiatric disorder prior to the patient's death	1.16	0.33	3.19	1.68–6.06	<0.01
Dissatisfaction with end-of-life caregiving					
Knowledge of physical symptoms and management	0.32	0.18	1.38	0.97–1.96	0.07
Time spent communicating with patients	0.44	0.20	1.55	1.05–2.30	0.03
Dissatisfaction with physicians' end-of-life care					
Treatment of physical symptoms	1.24	0.31	3.44	1.89–6.26	<0.01

Beta values indicate standardized regression coefficients on the final model after backward elimination. All variables were coded as: 0 = absence, 1 = presence. SE, standard error; OR, odds ratio; CI, confidence interval.