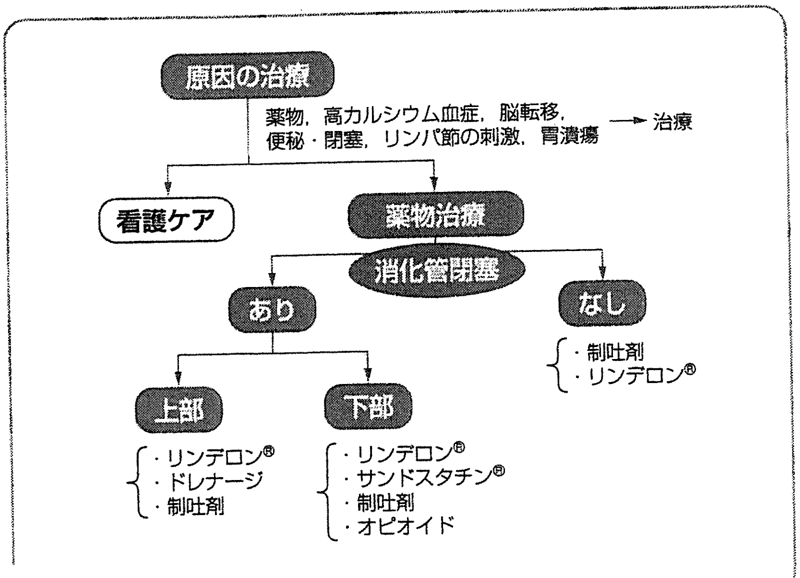

図9　嘔気・嘔吐の緩和治療

● 下部消化管閉塞の場合

・一般的に，経口摂取が一定量に制限できれば，絶飲食にせずに薬物療法単独で症状緩和が得られると考えられている．

・ステロイド＋分泌抑制薬（酢酸オクトレオチド）＋中枢性制吐剤＋患者の希望に合わせた経口摂取＋やや絞り気味の輸液＋オピオイドが一般的である．

・腹部膨満，疼痛には「持続する疼痛」に準じてオピオイドを使用する．腸蠕動を低下させたくない場合はフェンタニルが，腸蠕動を低下させることで鎮痛を図りたい場合にはモルヒネが推奨される．

・NGチューブ，輸液，口腔ケアについては上部消化管閉塞の場合と同様．

4 使用される薬剤

● ステロイド

・消化管閉塞全体として，「使用しないよりは使用する方がおそらく良い」再開通率がある．

・全身状態が許容できれば，ステロイドを投与し，効果があれば効果の維持できる最少量まで減量，または一旦中止して症状が悪化すれば再開する．効果がなければ中止する．

・1ヵ月以上の投与になる場合には，消化性潰瘍，耐糖能異常，満月様顔貌，精神症状，易感染性などのステロイドの副作用を生じるリスクが上がるため，利益が不利益を上回ると判断した場合に使用する．

● 消化管分泌抑制薬

・消化管閉塞全体を対象としたRCTでは，オクトレオチド酢酸塩（サンドスタチン®）がブチルスコポラミン臭化塩（ブスコパン®）より有意に優れた効果が認められている．

・上部消化管閉塞では有効な症例報告がある程度で，一般的には効果は10～20％以下である．

・下部消化管閉塞では，小腸の拡張が著明になる前から投与を開始する方が有効である．

● 制吐剤（表5）[4]

・完全閉塞の場合，メトクロプラミド（プリンペラン®）は症状を悪化させ，腸管内圧の上

表5 制吐剤の種類

抗精神病薬	ハロペリドール，プロクロルペラジン，クロルプロマジン
抗ヒスタミン薬	ヒドロキシジン，ジフェンヒドラミン，マレイン酸クロルフェニラミン
消化管蠕動亢進薬	メトクロプラミド，ドンペリドン
5-HT$_3$受容体拮抗薬	グラニセトロン，オンダンセトロン

（文献3）より一部改変）

昇による穿孔の危険があるため望ましくない．

・完全閉塞でないと考えられる場合，メトクロプラミドの持続点滴を蠕動が亢進しない程度で使用する．

・中枢性制吐剤を眠気の生じない範囲内で使用するとよい場合がある．例えばクロルフェニラミンマレイン酸塩（クロールトリメトン®），プロクロルペラジン（ノバミン®），ハロペリドール（セレネース®）など．

・いずれも投与開始後，症状緩和効果と眠気とのバランスを患者個々に判断して投与量を調節する．

癌性腹水による腹部膨満

1 癌患者における腹水

- 腹水のある患者の約10％の原因が癌である．

- 腹水は少量であれば無症状であるが，大量になると腹部膨満，腹痛，嘔気・嘔吐，下肢の浮腫，呼吸困難等の症状がみられる．

2 治療に際しての留意事項

- 腹水性状によって治療方法が異なることに注意する．

- 肝不全，転移性肝腫瘍による漏出性腹水は保存的治療が有効な場合があるが，一般的に癌性腹水は保存的治療に抵抗性である．

3 癌性腹水による腹部膨満に対する治療

- **腹腔穿刺・腹腔静脈シャント術**

・腹腔穿刺によるドレナージはタンパク喪失のリスクをともなうが，確実な症状緩和手段である．在宅でも行うことが可能である．

・全身状態が良い患者では腹腔静脈シャント術の適応となる場合がある．

- **輸液**

・観察的研究で，輸液量はやや脱水に置く方が腹水の貯留を有意に抑制できることが確かめられている．

・終末期で経口補給できない患者では，1日の水分負荷を経口量と合わせて1L以下を目安とし，浮腫や胸水など全身の溢水状態が増悪する前に対処する6)．

● 化学療法

- 腹腔内化学療法，全身化学療法が一部の患者で有効と考えられている．

4 使用される薬剤

● 利尿剤

- 癌性腹水の場合，利尿剤は腹腔穿刺よりも腎不全，電解質異常の合併率が高いので強くは推奨されない．
- ただし有効な場合があるので，肝転移による腹水に準じて利尿剤を投与して反応をみるのは初期治療として試す価値がある．
- 肝転移による漏出性腹水の場合, スピノロラクトン（アルダクトン®）±フロセミド（ラシックス®）の使用が勧められる．効果は3～7日後に出るため，特に投与初期は週1～2回は電解質と腎機能をチェックし，腎機能の悪化がみられたら利尿剤の適応は乏しい．

● アルブミン製剤

- 肝転移による漏出性腹水や感染症など一時的な低アルブミン血症の場合，アルブミン製剤＋利尿剤は経験的によく用いられてきた方法である．癌性腹水では推奨されない．

● オピオイド・抗不整脈薬

- 腹水量に働きかけずに腹満感を減らす方法として，少量のオピオイドが経験的に用いられている．
- 国内ではリドカイン，ケタミン塩酸塩が勧められることもあるが，国際的には標準的ではない．

倦怠感・食思不振

1 癌患者にみられる倦怠感・食思不振

● 全身倦怠感と食思不振は終末期癌患者によくみられる症状である．

● 食思不振の原因には可逆性のものもあるが，死に向かう過程において食思不振の出現は自然であることを認識しておく．

2 治療に際しての留意事項

● 倦怠感・食思不振の原因となっている病態を除外する．貧血，感染症，高カルシウム血症，

side MEMO　腎不全患者へのオピオイド投与

腎不全下ではモルヒネは有害な代謝産物が蓄積するので，せん妄やミオクローヌスなどを起こしやすくなる．
- モルヒネの少量投与であれば，症状に注意しながら継続投与
- 内服可能なら，オキシコドン経口薬に変更
- 内服不可能なら，フェンタニル（貼付薬，注射薬）またはオキシコドン注射薬（パビナール®）に変更

低ナトリウム血症，肝障害，口内炎，脳転移などが見逃されやすいが治療しうる病態である．

- 味覚障害があれば，ビタミンB群，亜鉛の補給を検討する．

3 倦怠感，食思不振に対する治療

● 消化管蠕動亢進薬

- ドンペリドン（ナウゼリン®）やメトクロプラミドは必ず毎食直前か24時間持続投与とする．食思不振に慢性嘔気をともなう時，肝腫大にともなう胃の拡張不全症候群がある時に60%で有効である．

● ステロイド

- 60%以上の患者で有意な食欲増進作用があるが，効果は短期間（2～6週間）しか持続しない．
- 1ヵ月以上になるとステロイドによる一般的な副作用のリスクが高くなるので，利益が不利益を上回ると判断される場合に選択できる方法である．

呼吸困難

1 癌患者にみられる呼吸困難

- 呼吸困難は終末期癌患者の約5割にみられる．
- 呼吸困難は疼痛と同じく主観的なものであり，理学所見や検査所見とは必ずしも相関しない．
- 呼吸困難は不安や死の恐怖につながりやすく，迅速かつ適切な説明と治療が必要である．

2 治療に際しての留意事項

- 一般治療で回復可能な要因を除外する．肺炎，心不全，不整脈，貧血，胸水，喘息など（表6）．
- 死亡直前に酸素飽和度はよいが頻呼吸で呼吸困難を訴える場合，代謝性アシドーシスによる死亡が迫っている可能性がある．
- 死亡直前期では気道分泌，浮腫，呼吸困難が増悪すれば輸液の減量（500mL以下）が推奨される[5]．特にルート確保のためだけの持続点滴はせん妄の原因にもなるため必須でなけ

表6　呼吸困難の原因

状況に関連した原因	急性不安
病状に関連した原因	疼痛，貧血，全身衰弱，肺塞栓，胸腔内感染，腹部膨満
癌に関連した原因	気管支の閉塞，癌の浸潤，癌性リンパ管症，上大静脈閉塞，胸水貯留
治療に関連した原因	気胸，肺切除，化学療法後の線維化，放射線治療後の線維化
その他の原因	喘息，肺気腫，心不全，心筋梗塞，不整脈，代謝性アシドーシス，異物誤飲

（文献3）より一部改変）

れば日中のみの間欠投与にする.

3 呼吸困難に対する治療（図10）

● ステロイド

- ステロイド投与はエビデンスのレベルは低いがよく行われる方法である．効果があれば有効量まで減量することが勧められる.
- ステロイドによる一般的な副作用に加えて，終末期では精神症状（せん妄）を惹起することがある．生じた場合にはステロイドを中止するか，継続するのであれば抗精神病薬を併用する.
- 気道狭窄，上大静脈症候群，多発肺転移では比較的効果がある場合がある．他の病態における作用機序は不明である.

● 抗不安薬

- 呼吸困難全体を対象とした抗不安薬の投与はRCTで有用性が不利益を上回らないのでルーチンでの使用は勧められない.「不安・焦燥状態を示す患者」でのみ併用が推奨される.
- 定型的にはアルプラゾラム（ソラナックス®）を頓用で使用してみて，よければ定期使用とする.
- 内服ができない時は，ジアゼパム（セルシン®）舌下投与，アタラックス®P皮下注または静注，セニラン®坐薬，ダイアップ®坐薬などが経験的に使用されている.
- 全身状態が良い患者では，SSRI（選択的セロトニン再取り込み阻害薬）を併用する.

● 吸入療法

- フロセミド（ラシックス®）の吸入は，現在RCTが行われているが否定的であり，「有意としても効果の幅は小さい治療」である.
- モルヒネなどの薬剤の吸入と生理食塩水の吸入では効果に差がみられていないため，生理食塩水の吸入でも良い.「何か方法がある」ということが患者の自己コントロール感につながり有用な場合が多い.

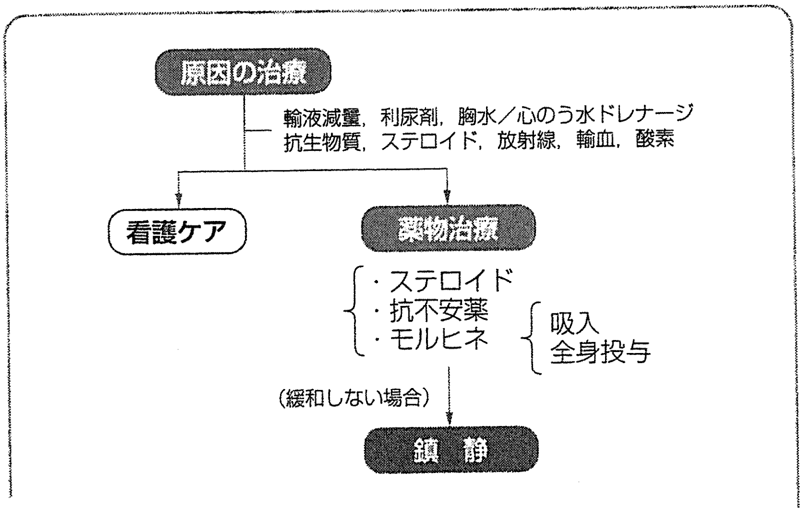

図10　呼吸困難の緩和治療

● モルヒネの全身投与

- 呼吸困難に有効であることが確かめられているオピオイドはモルヒネだけである．
- 呼吸困難にモルヒネを投与すると，効果の幅は少ないが有意な呼吸困難改善効果があることが確かめられている．
- 全身状態がよい場合には必ずしも意識やバイタルサインの低下を引き起こさないが，全身状態が不良な場合は「傾眠状態で苦痛がない」を目的とせざるを得ない場合も多くある．
- 経験的に，喀痰喀出困難のない多呼吸をともなう呼吸困難で最も有効である．
- 喀痰喀出困難による呼吸困難は喀痰管理ができないと薬物治療は困難．看取りの時期では臭化水素酸スコポラミン（ハイスコ®）で分泌抑制ができるが，鎮静され会話は困難になることが多い．
- 全身状態が不良の場合には，何を目的とするかで対処が異なるので，患者，家族と「意識を保って頑張る」のか，「眠気が出てもとにかく楽に」を目指すのかをよく相談する．

● 鎮静

- 様々な治療を行っても緩和できない苦痛症状に対しては，鎮静（セデーション）を考慮する．その適応についてはガイドライン7) に則り，多職種による検討を重ねて慎重に判断する．

せん妄

1 癌患者とせん妄

● 終末期患者に起こる認知障害には，せん妄と認知症という2つの病態があり，その鑑別が重要である．

● せん妄は癌患者の60～90％にみられる頻度の高い病態である．

● 患者のみならず家族にとっても苦痛が強いが治療可能であるため，せん妄の診断，治療は重要である．

2 治療に際しての留意事項

● 全身状態のスクリーニングを行い，感染症，脱水，電解質異常，肝不全，腎不全，低酸素血症，脳転移などを除外する（表7）4)．

● 投与薬剤（オピオイド，ベンゾジアゼピン系薬剤，抗うつ薬，H_2受容体拮抗薬など）をチェックする．それまで継続投与され副作用がなかったオピオイドがせん妄の原因になることは

表7　せん妄の原因

病状に関連した原因	疼痛，脱水，高カルシウム血症，低ナトリウム血症，腎不全，肝不全
癌に関連した原因	頭蓋内腫瘍，腫瘍随伴症候群
治療に関連した原因	オピオイド，向精神薬，抗うつ薬，H_2受容体拮抗薬，ステロイド，抗癌剤の中止（ニコチン，向精神薬など）
その他の原因	感染症，尿閉，低酸素血症，ビタミン欠乏症，頭部外傷

（文献4）より一部改変）

稀である.

- 原因治療が可能か不可能かによって，患者と家族の価値観を聞きながら，個別に目標を立てる.

3 せん妄に対する治療（図11）

● オピオイドローテーション

- 腎不全をともなう患者にモルヒネが投与されている場合，オキシコドンかフェンタニルへ変更する.
- 終末期の臓器不全によるせん妄はオピオイドローテーションだけでは改善は期待できないため，鎮痛を優先してモルヒネを継続してもよいことがある.

● 看護ケア

- コミュニケーションへの支援，環境整備，家族ケアなどが薬物以上に重要である.

● 薬物治療

- 基本的には抗精神病薬［ハロペリドール（セレネース®），リスペリドン（リスパダール®），フマル酸クエチアピン（セロクエル®）］の単独投与であるが，回復困難な終末期では睡眠を重視してベンゾジアゼピン系薬剤を併用する方がよい場合がある.

● 鎮静

- 様々な治療を行っても緩和できない苦痛症状に対しては，鎮静（セデーション）を考慮する．その適応についてはガイドライン6) に則り，多職種による検討を重ねて慎重に判断する.

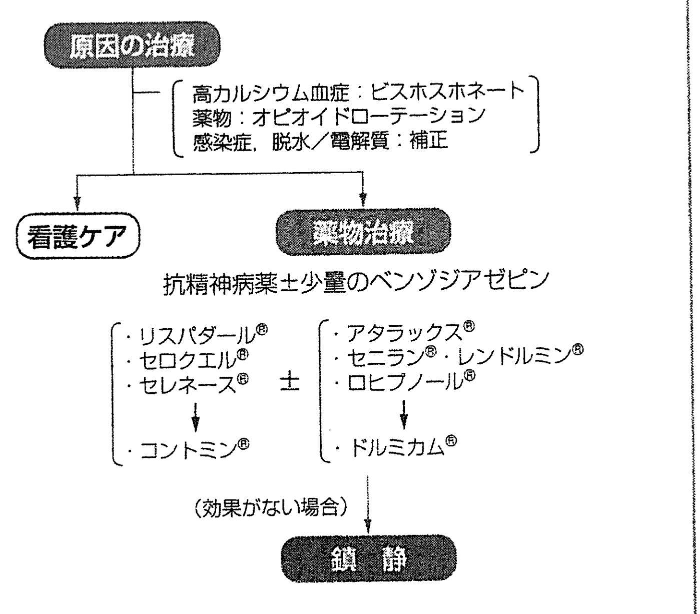

図11　せん妄の緩和治療

side MEMO　見落とされがちな副作用：錐体外路症状

副作用対策として用いられる薬剤（メトクロプラミド，ハロペリドール，プロクロルペラジンなど）が原因となって錐体外路症状を引き起こすことがしばしばあるので注意が必要である．症状として，不眠，焦燥感やイライラ感，手の震えなどがみられる．

結　語

- 癌患者によく見られる症状（痛み，嘔気・嘔吐，腹部膨満，倦怠感・食思不振，呼吸困難，せん妄）とその治療について概説した．
- すべての癌患者が適切な緩和医療を受けられるために，癌治療に関わる医療者は基本的な緩和医療の知識を身につけておくべきである．
- 癌患者の苦痛をやわらげるためには，様々な側面から患者を支援することが重要であり，そのためには多職種からなるチーム医療が不可欠である．

（天野功二／森田達也）

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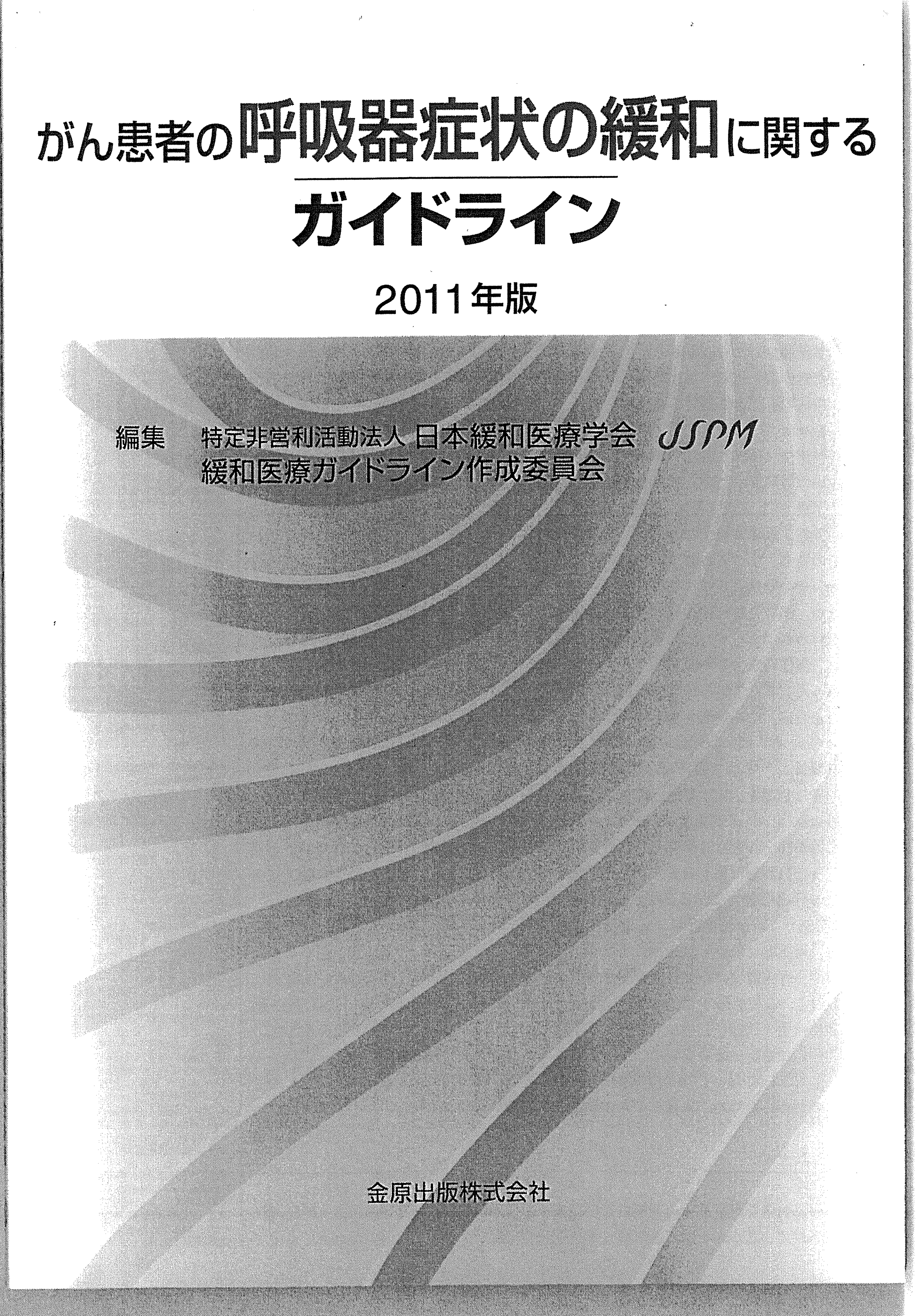

がん患者の呼吸器症状の緩和に関する ガイドライン

2011年版

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3 精神療法

観察研究において，呼吸困難と不安などの精神症状との関連が指摘されている。本項では，精神療法が呼吸困難の軽減に有効であるかについて概説する。

1 呼吸困難に対する精神療法

系統的レビューによると，がん患者の呼吸困難に対する精神療法の有用性を検討した無作為化比較試験は存在しない。ただし，COPDにおける呼吸困難に対する精神療法の有用性を検討した研究として，以下の2つがある1)。

Rosserら2)は，COPDを有する65例の患者を，8週間かけて施行する3種類の精神療法（精神力動的精神療法※1，支持的精神療法※2，看護ケア）のいずれか，あるいは対照群（1週間ごとに採血のみを行う）の計4群に無作為に割り付け，介入終了後，6カ月後にVAS（呼吸困難，抑うつ，不安）とFletcher scale（Hugh-Jonesの分類：耐運動能，P32参照），GHQ※3（精神疾患の有無）を用いて評価を行った。その結果，すべての群で治療終了後に呼吸困難の改善を認めたが，看護ケア群でのみ，その効果は6カ月後にも持続していた。精神症状は支持的精神療法群で改善したが，精神力動的精神療法群では改善しなかった。本研究では，症例数の計算などが行われておらず，症例数の不足のために効果が見出せなかった可能性がある。また，無作為割付も不適切で，対照群で抑うつ，不安が強かったという背景の相違があった。また著者らは，呼吸困難があるとはいえ不安についての治療を求めていない患者に，心理学的介入を提供することの妥当性に疑問を呈している。

Eiserら3)は，COPDを有する患者群において，グループ認知行動療法※4が不安を軽減し，ひいては呼吸困難を改善するかどうかを調査した。16例の安定したCOPD患者を，無作為化を行わずに，介入群に10例，対照群に6例を振り分けた。介入群は，5〜6例を1グループとして，精神科医による1回90分のグループ認知行動療法を毎週計6回行った。対照群では，呼吸機能検査を6週間にわたって毎週行った。評価は第1日目，介入終了後1週目，12週目に，VAS（6分間歩行テスト後の呼吸困難），MRC dyspnea scale（呼吸困難による支障の程度，P32注参照），SGRQ※5（呼吸器疾患による健康状態やQOLへの影響）を用いて行った。その結果，対照群においてはすべての生理学的検査，心理学的スコアの変化を認めなかったが，介入群においては6分間歩行距離試験が，介入終了後1週目において有意に改善し，この効果は12週目にも認められた。しかし主観的な抑うつ，不安，呼吸困難には全く改善を認めなかった。本研究についても，症例数が不足していること，無作為化を行っていないこと，その他多くの研究デザイン上の問題がある。

レビューにおいては，精神療法に関するカテゴリーには，これらの2研究しか含まれなかったため，エビデンスの強さは算出されなかった1)。

2 まとめ

がん患者を対象とする横断的観察研究などにおいて，不安と呼吸困難との関連が示されているが，その因果関係は依然明らかになっているとはいいがたい。よって

※1：精神力動的精神療法
洞察的精神療法の一種であり，患者の有する葛藤を明らかにし，転移感情の解釈を行ったり，精神療法中に生じた感情と幼少時に経験した感情を結び付けて過去の問題を治療関係のなかで扱うことで解決するといった手法を用いて治療を行う。一般的には年単位にわたって長期に行うことが定型とされるが，Rosserらは，それを身体疾患を有する患者に提供するために，短期間のプログラムとして実施している。

※2：支持的精神療法
患者と信頼関係を構築するなかで，感情表出の促進をしつつ，それを傾聴，受容，共感といった技術を用いて患者を支えることを中心とした精神療法である。洞察的精神療法などと比較すると，患者に変化を迫るというよりもむしろ現在の患者を肯定的に受け止め，また現在有している能力を強化するといった点に特徴がある。精神力動的精神療法のなかで転移解釈を行わないものを支持的精神療法と定義している。

※3：GHQ（General Health Questionnaire）
精神障害のスクリーニングを目的として開発された，30項目からなる自記式質問票である。

※4：グループ認知行動療法
認知行動療法とは，患者が直面している問題に関連する不適応な認知および行動のパターンに焦点をあて，治療者との精神療法的交流や行動実践などを通して適応的な認知・行動を学習することによって，精神的苦痛を軽減する治療法である。グループ認知行動療法とは，複数の患者を対象として，ひとつの構造のなかで本治療方法を提供することをいう。Eiserらの研究では，身体症状や病気が心理的側面に与える影響などがどのように生活に影響を与えているのかを話し合うなかで，不安やそのコントロールについて理解を深めるような治療を行った。また，呼吸法や筋弛緩法といったリラクセーション法も施行した。

※5：SGRQ（St George's Respiratory Questionnaire）
呼吸器疾患による健康状態やQOLへの影響を評価するための，50項目からなる自記式質問票である。

がん患者の呼吸困難の治療にあたっては，まずは身体的側面からの対応が優先されるべきであると思われる。

不安によって呼吸困難が増強しているように観察される患者に対しては，不安などの精神的負担の軽減を目的に精神療法を行い，副次的に呼吸困難の改善を目的とする場合があるかもしれない。しかしその場合にも，Rosser らが指摘するように患者自身の精神療法を受けたいという意向が重要となるのはいうまでもない2)。また終末期であれば，呼吸困難のために長時間にわたる会話が困難となり，精神療法の適応となりにくいことも留意するべきである1)。

（奥山　徹）

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Patients' Supportive Care Needs and Psychological Distress in Advanced Breast Cancer Patients in Japan

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Objective: Few studies have investigated the prevalence of the unmet needs among advanced or recurrent breast cancer patients in Asian countries and little is known about the relation between their unmet needs and psychological distress/quality of life.
Methods: The participants ($n = 87$) comprised randomly selected ambulatory female patients with advanced or recurrent breast cancer attending the Outpatient Department of Oncology, Immunology and Surgery of Nagoya City University Hospital. The patients were asked to complete self-administered questionnaires assessing the level of their physical and psychological symptoms, supportive care needs and socio-demographic and biomedical factors. The association between the patients' perceived needs and psychological distress/quality of life was then analyzed statistically.
Results: The patients had a mean ± standard deviation of 11 ± 7.7 and a median of 10 unmet needs. The prevalence of the 17 most frequent unmet needs was over 50%, and almost all of these unmet need items belonged to the Psychological or the Health system and information domain. The total Short-form Supportive Care Needs Survey Questionnaire with cancer score was significantly associated with the indices of psychological distress and quality of life. Most of the Short-form Supportive Care Needs Survey Questionnaire with cancer domains except Sexuality domain were also significantly associated with all the indices of psychological distress.
Conclusions: Psychosocial needs were strongly associated with psychological distress and quality of life. Quality of life and psychological distress may be improved if interventions for unmet needs, especially psychological and information needs, are made.

Key words: psycho-oncology — needs — psychological distress — quality of life — supportive care

INTRODUCTION

In Japan, breast cancer is the most common cancer among women, with 40 000 women being affected annually (1). The psychosocial impact of breast cancer deserves much clinical and research attention not only because of this high prevalence but also because of the magnitude of distress associated with the disease itself, treatment and the long duration of illness.

As a matter of fact, psychological distress, including anxiety and depression, are common among breast cancer patients, even years after diagnosis and treatment. The prevalence of psychiatric diagnoses (mainly depression and anxiety) among breast cancer patients reportedly ranges from around 20 to 40% (2–5). These psychological factors have been reported to predict subsequent quality of life (QOL) (6).

Women with advanced breast cancer, in particular, have high rates of psychiatric and psychological disturbances. A previous study showed that 42% of 227 women with advanced breast cancer had at least one psychiatric disorder and 36% had clinical depression and/or anxiety (3). Another study reported that 45% of the patients with recurrent breast cancer developed diagnosable depression and/or anxiety disorder within 3 months of their cancer diagnosis (4). Yet, another study showed that 42% of the patients with an initial breast cancer recurrence met the diagnostic criteria for major depressive disorder or adjustment disorder (5). Nevertheless, a previous study demonstrated that the distress of these patients remains inadequately diagnosed and treated (7). Furthermore, various barriers to the expression of psychological concerns among cancer patients have been reported (8).

Specific issues of needs as well as their perceived magnitudes should also be directly evaluated by need assessments. Such assessments are often used as a first step in the design of interventions to meet patients' needs (9–14). Evaluating patients' needs is important because unmet needs are correlated with a low QOL (15), since paying attention to psychosocial needs is associated with the satisfaction of patients with their medical care (16) and because unwanted interventions that do not match personal needs can have harmful effects. Inadequate attention to the needs of patients and their families may also lead to increased health care costs and unnecessary distress (17).

Few studies, however, have investigated the prevalence of the unmet needs among advanced or recurrent breast cancer patients in Asian countries. In past studies conducted in occidental countries, 20–40% of the incurable cancer patients were shown to have unmet needs in psychological and medical communication/information areas, in addition to 20–30% with physical unmet needs (18–21). For advanced breast cancer patients, the highest prevalence of unmet needs was observed in the psychological and health information domains (22).

Although some effective interventions for improving psychological distress, such as cognitive therapy, multifaceted psychosocial intervention and supportive care intervention (23–25), as well as pharmacotherapy, are available, these interventions are not always easy to provide in busy clinical oncology settings. Thus, brief and effective interventions are needed for cancer patients. Negative attitudes toward mental illness and psychological problems also remain a problem among cancer patients (26). By using an unmet needs assessment, rather than a direct mood assessment, we may be able to develop new interventions that are easily accepted by patients. However, little is known about the relation between patients' unmet needs and psychological distress and/or QOL in advanced cancer patients.

The purposes of the present study were to report the frequency of unmet needs in advanced breast cancer patients and to investigate the association between patients' unmet needs and psychological distress/QOL. We hypothesized that the prevalence of unmet needs would be high among them and a greater than moderate association would exist between the patients' perceived needs and psychological distress/QOL.

PATIENTS AND METHODS

SUBJECTS

The study subjects were ambulatory female patients with advanced breast cancer who attended the outpatient clinic of the Oncology, Immunology and Surgery Department of Nagoya City University Hospital. Potential participants were sampled at random using a visiting list and a random number table.

The eligibility criteria for inclusion in the study were as follows: (i) women with a breast cancer diagnosis, (ii) an age of 20 years or older, (iii) informed of the cancer diagnosis, (iv) well enough to complete the survey questionnaire [Eastern Cooperative Oncology Group (ECOG) performance status of 0–3] and (v) clinical stage of breast cancer is IV or recurrence. The exclusion criteria included (i) severe mental or cognitive disorder, or (ii) an inability to understand the Japanese language.

This study was approved by the Ethics Review Committee of Nagoya City University Graduate School of Medical Sciences, Japan, and was conducted in accordance with the principles laid down in the Helsinki Declaration. Written consent was obtained from each patient after the provision of a thorough explanation of the purpose and method of the study.

PROCEDURE AND MEASURES

After informed consent had been obtained, the patients were asked to complete the self-administered questionnaires described below while they were at home and to return them on the next day. In the case of incomplete answers, clarifications were sought over the telephone.

PATIENT'S PERCEIVED NEEDS: SHORT-FORM SUPPORTIVE CARE NEEDS SURVEY QUESTIONNAIRE WITH CANCER

The Short-form Supportive Care Needs Survey Questionnaire (SCNS-SF34) with cancer consists of 34 items covering five domains of need: psychological (10 items), health system and information (11 items), physical and daily living (5 items), patient care support (5 items) and sexuality (3 items). Respondents were asked to indicate the level of their need for help over the last month in relation to their having cancer using the following five response options [1, no need (not applicable); 2, no need (satisfied); 3, low need; 4, moderate need; 5, high need]. The subscale scores were obtained by summing the individual items. In addition, the total score was obtained by summing all the subscale scores (range, 34–170). Higher scores indicated a higher perceived need. As an alternative use, the scale can be used to obtain information on the presence/absence and number of the perceived unmet needs (a rating of 3 or higher was regarded as unmet need), depending on the researcher's clinical question. The validity and reliability of the Japanese version of the SCNS-SF34 have been established (27).

Psychological Distress: Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS) is used to detect the states of depression and anxiety in medically ill patients, and questions about physical symptoms are excluded. This scale is composed of a self-reported questionnaire consisting of 14 items, and subjects rate how they felt during the previous week using a four-point Likert scale. The HADS consists of an anxiety and a depression subscale (0–21 points each), and the total score can range from 0 to 42. Higher scores indicate more severe depression and anxiety (28). The Japanese version of the HADS has been validated for cancer populations (29). The optimal screening cut-off point for adjustment disorder and/or major depressive disorder was 10/11, whereas the cut-off for major depression was 19/20.

QOL: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30

Patient's QOL was assessed using the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30). The EORTC QLQ-C30 is a 30-item self-reported questionnaire covering functional and symptom-related aspects of QOL for cancer patients. The validity and reliability of the Japanese version of the EORTC QLQ-C30 have been confirmed (30). In this study, the Global Health Status score was used. Higher Global Health Status scores indicate a higher QOL.

Socio-demographic and Biomedical Factors

An *ad hoc* self-administered questionnaire was used to obtain information on socio-demographic factors, including the marital status, level of education and employment status. The ECOG performance status was evaluated by the attending physicians. All other medical information (duration since diagnosis, clinical stage and anti-cancer treatment) was obtained from the patients' medical records.

Statistical Analysis

To investigate the association between the patients' perceived needs and psychological distress and/or QOL, the Spearman correlation coefficients and their 95% confidence intervals were calculated. All statistical procedures were conducted using the SPSS 17.0J version software for Windows (SPSS Inc., 2008)

RESULTS

Patient Characteristics

A random sample of 87 patients was identified. Two patients were excluded: one because she refused to participate and one for not providing responses despite consenting to participate. The socio-demographic and clinical characteristics of the remaining 85 patients (response rate: 97.7%) are shown in Table 1.

More than 80% of the subjects suffered from recurrent breast cancer, and about 90% of the patients did not have any impairment of physical functioning. The mean ± standard deviation (SD) and median number of months after the initial breast cancer diagnosis were 63.2 ± 78.4 and 42.8 (0–597.2), respectively. Among the participants, 74 patients (87.1%) had received surgery, 69 patients (81.2%) had received chemotherapy and 59 patients (69.4%) had received hormonal therapy.

Table 1. Characteristics of study participants ($n = 85$)

Characteristics	n	Percent
Age (years)	Mean: 58.6 (SD = 11.9), median: 59 (range, 32–89)	
Marital status		
Married	68	80
Employment status		
Full-time/part-time	29	22.6
Clinical stage		
IV	13	15.3
Recurrence	72	84.7
Performance status		
0	58	68.2
1	19	22.4
2	4	4.7
3	4	4.7
4	0	0
Current anti-cancer treatment		
Surgery	7	8.2
Chemotherapy	40	47.1
Trastuzumab	12	14.1
Hormonal therapy	34	40
Radiation therapy	0	0
HADS total score	Mean: 11.0 (SD = 7.54), median: 10.0 (range, 0–36)	
Adjustment disorder defined by HADS	28	32.9
Major depressive disorder defined by HADS	12	14.1

HADS, Hospital Anxiety and Depression Scale.

FREQUENCY OF UNMET NEEDS

Each patient scored a mean of 11 (SD = 7.7) and a median of 10 unmet needs. Table 2 shows the most common unmet needs (rated 3 or more on the five-point Likert scale). The most common unmet need was 'Fears about the cancer spreading' (78.8%) followed by 'Feeling I can do nothing about the result of treatments', 'Having one member of hospital staff with whom you can talk to about all aspects of your condition, treatment and follow-up', 'Being afraid of worried by people around' and 'Being informed about things you can do to help yourself to get well'. The prevalence of the 17 most frequent unmet needs were over 50%, and almost all of these unmet need items belonged to the Psychological domain or the Health system and information domain.

NEEDS BY DOMAIN

The mean/median numbers of unmet needs in each domain were as follows: Psychological needs (total of 10 items), 6.3/8; Health system and information needs (total of 11 items), 6.1/7; Physical and daily living needs (total of 5 items), 2.1/2; Patient care and support needs (5 items), 2.3/2; Sexuality needs (3 items), 0.4/0.

ASSOCIATION BETWEEN PATIENTS' PERCEIVED NEEDS AND PSYCHOLOGICAL DISTRESS AND/OR QOL

The total SCNS-SF34 score was significantly associated with both psychological distress (HADS total: $r = 0.65$, $P < 0.01$; HADS anxiety: $r = 0.66$, $P < 0.01$; HADS depression: $r = 0.57$, $P < 0.01$) and QOL (Global Health Status: $r = -0.53$, $P < 0.01$). Each needs subscale score of the SCNS-SF34, including Psychological, Health system and information, Physical and daily living and Patient care and support, was significantly associated with all the types of psychological distress evaluated in the current study (anxiety, depression and total HADS score). The correlation coefficients ranged from 0.42 (the association between HADS depression and information need, $P < 0.01$) to 0.69 (the association between HADS total and psychological need, $P < 0.01$). Regarding the relation between patients' needs and QOL, each needs score of the SCNS-SF34, including Psychological, Health system and information, Physical and daily living and Patient care and support, was also significantly associated with the Global Health Status. The correlation coefficients ranged from -0.41 (the association between Global Health Status and information need, $P < 0.01$) to -0.69 (the associations between Global Health Status and Physical and daily living need and Psychological need, $P < 0.01$) (Table 3).

DISCUSSION

Advanced breast cancer patients had many unmet needs, and half of the SCNS-SF-34 items were unmet in more than 50% of the patients. Most of the common unmet need items belonged to the Psychological domain or the Health system and information domain. In addition, patients' needs were strongly associated with psychological distress and moderately associated with QOL.

To the best of our knowledge, the present report is one of the few studies to investigate the prevalence of unmet needs among patients with advanced breast cancer. The prevalence of unmet needs found in our study is nearly two times as high as those in previous reports examining patients with advanced cancer (21,22). An Australian study investigated the needs of 105 metastatic breast cancer patients using SCNS and found that the prevalence of unmet needs in the psychological domain was between 24 and 41%, whereas the prevalence of unmet needs in the information domain ranged from 26 to 41% (22). A British study showed that the prevalence of unmet needs among 246 patients with mixed advanced incurable cancer assessed using the Need Assessment for Advanced Cancer Patients (NA-ACP) was 39–40% for unmet needs in the psychological or emotional domain and 31–35% for unmet needs in the medical communication and information domain (21).

A larger number of unmet needs were observed in the present study, compared with previous studies. The findings may indicate that there are fewer social supports available for patients with advanced breast cancer in Japan (31). In addition, although differences in symptom reporting among culture were limited (32), there may be variances when people report their perceived needs. To consider the discrepancy among cultures, further studies which find out patients' perceived needs from cross-cultural viewpoints are needed.

This is the rare study to examine the association between the unmet needs of patients with advanced breast cancer and psychological distress and/or QOL. We found a significant correlation between unmet needs and psychological distress and/or QOL. As this was a cross-sectional study, conclusions regarding the causal correlation cannot be made. However, our findings suggested that interventions based on unmet needs might reduce the distress of advanced cancer patients and enhance their QOL.

A brief nurse-delivered intervention addressing the needs of 105 women with advanced breast cancer was reported in Australia. This intervention consisted of identifying individual unmet needs and information, coaching and practicing self-care and communication strategies, and the distribution of relevant information cards. However, no significant differences between the intervention and usual care groups were observed (33). Another trial obtained feedback on patient-reported outcomes, with patient-reported outcomes summarized on feedback sheets. For the intervention groups, the information on the feedback sheet was sent to a telephone caseworker or the patient's oncologist/general practitioner. However, no overall intervention effects were observed (25). These results suggest that interventions targeting only the

Table 2. Items of moderate/high unmet needs among advanced breast cancer patients ($n = 85$)

Rank	Item	Percent (moderate/ high need)[a]	95% CI	Domain
1	Fears about the cancer spreading	78.8	70–88	Psychological
2	Worry that the results of treatment are beyond your control	71.8	62–81	Psychological
3	Concerns about the worries of those close to you	68.2	58–78	Psychological
4	Having one member of hospital staff with whom you can talk to about all aspects of your condition, treatment and follow-up	67.1	57–77	Health system and information
5	Being informed about things you can do to help yourself to get well	65.9	56–76	Health system and information
5	Anxiety	65.9	56–76	Psychological
7	Feeling down or depressed	62.4	52–73	Psychological
7	Uncertainty about the future	62.4	52–73	Psychological
7	Feeling about death and dying	62.4	52–73	Psychological
10	Having access to professional counseling if you, family or friends need it	57.6	45–66	Health system and information
11	Feelings of sadness	56.5	46–67	Psychological
11	Learning to feel in control of your situation	56.5	46–67	Psychological
11	Reassurance by medical staff that the way you feel normal	56.5	46–67	Patient care and support
11	Being informed about your test results as soon as feasible	56.5	46–67	Health system and information
15	Being adequately informed about the benefits and side effects of results before you choose to have them	55.3	45–66	Health system and information
15	Being treated in a hospital or clinic that is as physically pleasant as possible	55.3	45–66	Health system and information
17	Being informed about cancer which is under control or diminishing	54.1	44–65	Health system and information
17	Being treated like a person not just another case	54.1	44–65	Health system and information
19	Being given written information about the important aspects of your care	52.9	42–64	Health system and information
20	Keeping a positive outlook	49.4	39–60	Psychological
21	Lack of energy/tiredness	48.2	38–59	Physical and daily living
21	Being given information about aspects of managing your illness and side effects at home	48.2	38–59	Health system and information
21	Being given explanations of those tests for which you would like explanations	48.2	38–59	Health system and information
24	More choice about which cancer specialists you see	47.1	36–58	Patient care and support
25	Not being able to do the things you used to do	45.6	35–56	Physical and daily living
26	Hospital staff acknowledging, and showing sensitivity to, your feelings and emotional needs	44.7	34–55	Patient care and support
27	Hospital staff attending promptly to your physical needs	43.5	33–54	Patient care and support
28	Pain	42.4	32–53	Physical and daily living
28	More choice about which hospital you attend	42.4	32–53	Patient care and support
30	Feeling unwell a lot of the time	38.8	28–49	Physical and daily living
30	Work around the home	38.8	28–49	Physical and daily living
32	Changes in sexual feelings	15.3	8–23	Sexuality
32	Changes in your sexual relationships	15.3	8–23	Sexuality
34	To given information about sexual relationships	10.6	4–17	Sexuality

CI, confidence interval.

[a] Moderate/high unmet need: rated 3 or more on the five-point Likert scale on each item of the Short-form Supportive Care Needs Survey Questionnaire.

Table 3. Association between patients' unmet needs (SCNS-SF34) and psychological distress (HADS)/quality of life (EORTC QLQ-C30 Global health status)

	Spearman's correlation coefficient				
	SCNS-SF34				
	Physical and daily living domain	Psychological domain	Sexuality domain	Patient care support domain	Health system and information domain
HADS total	0.59 (0.43–0.71)*	0.69 (0.56–0.79)*	0.19	0.51 (0.33–0.65)*	0.52 (0.34–0.66)*
EORTC QLQ-C30 Global health status	−0.69 (−0.55 to −0.79)*	−0.45 (−0.26 to −0.61)*	0.12	−0.44 (−0.60 to −0.25)*	−0.41 (−0.57 to −0.22)*

EORTC QLQ-C 30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30.
*$P < 0.01$.

assessment of unmet or special needs may not be useful for improving the psychological distress of patients with advanced breast cancer. Case management based on several unmet needs, including physical unmet needs, is needed.

This study has several limitations. First, as our study used a cross-sectional design, we cannot be sure of the cause–effect relationship. Distress may create unmet needs, or unmet needs may generate distress; alternatively, a third factor may give rise to both unmet needs and distress. Second, the observed correlations among needs, distress and QOL may not be causal at all but simply represent conceptual overlaps among the respective measures. Third, because we invited outpatients to participate in the present study, most of the patients did not have any physical functioning impairments. Thus, our results do not reflect the unmet needs of advanced cancer patients with severe physical impairment. Finally, the sample size was not sufficiently large to use more rigorous statistical analyses such as multiple regression analysis, limiting the generalizability of these results to all advanced breast cancer patients.

Despite these limitations, this study has some important strengths. We used well-validated and reliable tools to assess psychological status and QOL, which should help to obtain generalizable results. We also selected the patients who have the same cancer type (breast cancer), similar physical status and advanced cancer to match QOL and needs, so we concentrated on a homogenous sample of patients. In addition, only a few patients refused to complete the questionnaires.

The present study revealed close associations among the various domains of unmet needs, psychological distress and QOL among patients with advanced breast cancer but without grave physical impairments. Clinicians must pay greater attention to unmet needs and provide appropriate services and resources. However, we do not know what kind of services and resources are suitable for these unmet needs now. Given the multitude of unmet needs among these patients, multifaceted interventions targeting various domains of unmet needs should be developed and tested to decrease the psychological distress of these patients.

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Conflict of interest statement

Toshiaki Furukawa daclares that he has received honoraria for speaking at CME meetings sponsored by Astellas, Dai-Nippon Sumitomo, Eli Lilly, GlaxoSmithKline, Janssen, Kyorin, MDS, Meiji, Otsuka, Pfizer, Shionogi and Yoshitomi. He is on the advisory board for Sekisui Chemicals and Takeda Science Foundation. He has received royalties from Igaku-Shoin, Seiwa-Shoten, Nihon Bunka Kagaku-sha and American Psychiatric Publication. The Japanese Ministry of Education, Science, and Technology and the Japanese Ministry of Health, Labor, and Welfare have funded his research.

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quetiapine, aripiprazole, blonanserin), antidepressants (fluvoxamine, sertraline, paroxetine, milnacipran, mirtazapine) and thyroxine, her mood fluctuated frequently, including nine depressive phases and five hypomanic phases in the 26 months after the first admission, with euthymic periods lasting less than 3 weeks. Several drugs could not be used to sufficient doses due to side-effects; however, most drugs were used to adequate doses and durations. Consequently, she was admitted eight times (total duration: 332 days) due to depressive episodes. On her third and fifth admissions, six bilateral ECT sessions were performed consecutively for acute-phase severe depressive symptoms and moderate improvement was observed. During these two ECT sessions, medications were not changed. In consideration of the outcome of the two previous acute-phase ECT sessions, ambulatory continuation-ECT was started 26 months after the first admission. Continuation-ECT was administered weekly for the first month and subsequently reduced to biweekly administration. In the subsequent 12 months of C/M-ECT, she did not reach remission; however, her HRSD score decreased to 14 and her YMRS score decreased to 7, indicating reduced severity of depression and decreased hypomanic state. To date, she has not been hospitalized.

Antidepressants, particularly tricyclic antidepressants, are reportedly responsible for inducing 20% of RC cases;[1] however, in our patient, most hypomanic phases occurred when she was antidepressant-free. Regarding the C/M-ECT schedule, we could not extend beyond 2-week treatment intervals, which is similar to a report indicating that maintenance-ECT could not be extended beyond 3-week treatment intervals for patients with BD.[2] Although she did not achieve complete remission, our experience suggests that C/M-ECT could reduce the likelihood of re-admission by decreasing the severity of RC, thereby providing a cost-effective treatment. Except for one naturalistic study of 14 RC patients,[3] research on the effectiveness of C/M-ECT is limited. In order to evaluate the efficacy of C/M-ECT and establish a standard protocol for BD, further study in a large sample or in a controlled study is needed.

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Case of intrathecal baclofen-induced psychotic symptoms

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BACLOFEN, AN ANTAGONIST of inhibitory neurotransmitter gamma-aminobutyric acid (GABA) receptors, is currently the most widely used drug for the treatment of spasticity. Intrathecal baclofen (ITB) is approved for the treatment of spasticity of spinal or cerebral origin in patients who are intolerant of, or unresponsive to, oral baclofen. To the best of our knowledge, the extant literature reporting psychiatric symptoms co-occurring with ITB therapy in adults is limited.[1] We report herein a case of psychotic manifestations induced by ITB administration. We have obtained the oral consent of this patient to report her case.

Mrs A was a woman in her 50s who had neither a family history nor a personal history of psychiatric illness. In the year 200X-5, she received a head injury in a traffic accident and was diagnosed as having diffuse axonal injury. She subsequently suffered from limb dystonia, and ITB therapy was started in December 200X-1. Her physician temporarily increased the baclofen dose to 1400 μg/day, which is regarded as the maximum dosage (the normal therapeutic dose is up to 250 μg/day), due to pain and rigidity of limbs. Negativism, delusions concerning her own name ('My name is B, not A!') and her husband ('I have already divorced him, and I have another husband'), persecutory delusions of being observed and poisoned, delusions of interpretation, and acousma appeared a few days after the baclofen dosage was increased to the maximum value. Therefore, the physician decreased the baclofen dosage to 250 μg/day. However, the patient's hallucinations and delusions did not improve. She had difficulty with daily living because of her psychotic symptoms, and she had to be admitted involuntarily to the inpatient ward of psychiatry in April 200X. Olanzapine (maximum dosage of 20 mg/day) and risperidone (maximum dosage of 8 mg/day) were both administered, but neither of these treatments was effective. Finally, her psychotic symptoms improved dramatically when we reduced the baclofen dosage to 50 μg/day in May 200X. The patient's blood laboratory data and a cranial computed tomography scan were within the normal limits; the patient refused to undergo an electroencephalogram. The patient remembered the episode after her symptoms had disappeared, commenting, 'I felt that I was in a long dream.' In December 200X, she requested to re-increase her baclofen dosage because of stiffening and pain in her limbs. Psychotic symptoms similar to her previous episode re-appeared when the baclofen dosage was re-increased to 80 μg/day, which then subsided only after the dosage was decreased to 50 μg/day.

We clinically determined that her diagnosis was not delirium for the following reasons. At first, her symptoms did not completely meet with the DSM-IV diagnostic criteria. For example, her condition was not fluctuating and there was no circadian variation. In addition, neither the sleep–wake rhythm disturbance nor decrease of alertness was observed. Recurrence of the psychiatric episode after re-increase of the baclofen dosage supports the view that ITB intoxication