IV. 研究成果の刊行物・別刷



# 美容による心理的・身体的効果

## 1 はじめに

美容による心理的・身体的効果は何か。一見難しいこの問いに対して、実は、 私たちは日常生活の行動の中で答えを出していることが多い。

例えば、試験の失敗や失恋など心の痛手から気分を一新したいとき、ヘアスタイルや洋服、化粧方法などを変えるのは昔からの常套手段である。また、少し疲れて元気のない朝は、化粧をすることで気分が引き締まり、学校に行ったり友人との待ち合わせに出かけられたという経験をもつ人も多いはずである。反対に、身体が疲れすぎたり、気分が落ち込みすぎてしまったときは、エステティックマッサージの施術を受けたり、一人でアロマバスに入ってくつろぐことで心身の回復を実感することもある。このうち、化粧などは主として気分の高揚を担う、積極的な美容行為であるのに対して、エステティックマッサージなどは主として気分の鎮静を担う、癒しの美容行為なのである。

近年、美容のさまざまな効果は、心理学研究や医学研究を通じて解明されつつ ある。しかし、私たちはそれ以前から誰に教わることもなく、これらの行為を使 い分けて生活してきた。現在では、これらの効果を積極的に利用して、高齢者や 障害者の福祉に役立てられないか、その人らしく生きることのお手伝いをさせて いただけないか、という観点から美容福祉を考え、実践していこうとしている。

ここでは、美容福祉の実践に役立つための基礎知識として、美容の心理的・身体的効果に関する研究を紹介する。

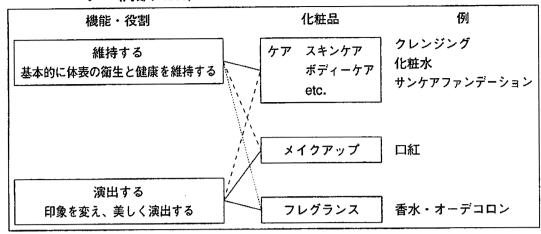
## 2 美容技術の分類

化粧、ヘア、ネイル、ファッション、アロマテラピー、エステティックマッサージなど美容福祉で用いられる技術は、次の二つの機能・役割を有している。

つは、身体の衛生や健康を維持するための"維持機能"であり、もう一つは、



●図 1 −10 化粧の心理学を考えるうえでの化粧の機能およびそれを支える化粧品のカテゴ リー(阿部、1993)



人の印象を変え、美しく演出するための"演出機能"である。個々の技術は、この両方の機能をもつため、そのどちらを重視するかによって、もたらされる心理的・身体的効果も異なる。例えば、化粧に関しては図1-10のようになり、ほかの美容技術の心理的・身体的効果も、その機能の類似性から同様に考えることができる。したがって、ここでは化粧(スキンケア、メイクアップ)について説明するが、これはほかの美容行為にも当てはまる。例えば、メイクアップに近いものとして、ヘア、ネイル、ファッション、ケアに近いものとして、アロマテラピーやエステティックマッサージがある。

## 3 化粧の心理的効果

化粧には、その人以外の他者に与える心理的効果(=対他者的効果)と、自信 や満足感の上昇といったその人自身に生じる心理的効果(=対自己的効果)があ る。

#### (1) 対他者的効果

外見を美しく装うことは、まわりの人の判断や行動にどのような影響を与えるのか。人は、同一人物の写真を見せられた場合、化粧をしている方が素顔の方よりも魅力的だと判断しやすいことが、これまでの研究から明らかになっている。もちろん、すべての場合にあてはまるわけではない。有能な秘書かどうかなど、求められる職業の内容によっては、入念な化粧がその女性の能力評価にマイナス

に作用することや、評価者としては、女性の方が男性より厳しいことも報告されている。

しかし、このように人を判断するという場面だけでなく、人を援助するという場面でも、化粧や服装の効果が認められている。例えば、ミンスら (1975) がキャンパス内で本をばらまいて困った様子をみせるという実験を行ったところ、同一人物であっても身なりを整えていたときの方が、男性からの援助行動(拾うのを手伝うなど)が明らかに多かった。

なぜこのように他者の評価や行動は変わるのだろうか。それは、化粧を施すことによって客観的な魅力度が上昇することに加えて、「手入れをする人=よい人= 好ましい人格」であると受け取られるためであると考えられている。

このように、とりわけ初対面の場合、外見の印象は、まわりの人の判断や行動 に影響を与えやすいのである。

## (2) 対自己的効果

化粧をした人自身に生じる心理的効果には、「気分の高揚効果と鎮静効果」という、相反するものが認められている。例えば、朝は「スッキリとした」気分にさせてくれるスキンケアが、同じ行為なのに、夜は「ほっとした」気分にさせてくれることは、研究結果を明示するまでもなく、多くの人が実感することであろう。

#### ① 化粧による気分変化

化粧をすることによって生じる主な気分変化には、次の五種類がある(字山ら、1990)。もっとも、これらの気分は化粧によって誰にでも均一に生じるのではない。「攻めの化粧から守りの化粧へ」といわれるように、20歳代は積極的な気分になり、50歳代はリラックスするなど、年代やパーソナリティ、化粧を行う具体的生活場面などにより、比重を変えて現れる。そして、この五つの気分変化も、一見矛盾する化粧の心理的効果、「気分高揚効果」(a・c・d)と「気分鎮静効果」(b・e)に大別することができる。

- a. 積極性の上昇 例:人に会いたくなる、何かしたくなる、外に出たくなる
- b. リラクゼーション 例:くつろぐ、リラックスする、穏やかになる
- c. 気分高揚(対外的) 例:表情が明るくなる、明るくなる、やる気が出る
- d. 気分高揚(対自己的) 例:晴れ晴れする、うれしい、自分が好きになる
- e. 安心 例:安心する、恥ずかしくない

心の健康 ・自己愛撫の快感 ・変身願望の充足 ・ 創造の楽しみ 化粧行為自体がもつ満足感 極 ストレス解消 ・快い緊張威 的 信 自 己 化 Ϋ́ 外見的欠陥の補償 表 現 自 外見的評価の上昇 ・異性への魅力度上昇 同性への優越意識 対 2 人行 粧 自己顕示欲の充足 充 動 周囲への同調・期待への対応 実 社会的役割への適合 戚 伝説的性役割に基づくアイデンティティ 対人的効用

●図1-11 化粧行動のもつ心理的効用の構造(松井ら、1983)

## ② 化粧の心理的効用

化粧は、その人にとってどのような意義があるのだろう。松井ら(1983)は、社会心理学の視点から、"化粧行為そのものがもたらす効果"と"他者の存在を前提として生じる効果"に分けて説明した(図1-11)。前者は、鏡に向かい自分の顔に触れる心地よさ、変化の中で満たされていく変身願望など、人に見られるということ抜きで純粋に化粧行為を楽しむとき、どのような気持ちになるかを表わしている。これに対して後者は、にきびやしみなどの顔のトラブルを隠すことで、安心してより積極的に人とつき合えるなど、他の人の存在を前提にして初めて意味を有する心理的効果である。また、化粧によって女性らしさを示したり、あるいは、キャリアウーマンにふさわしい身なりや化粧をすることで、周囲からの信頼を得て、自信をもって求められる役割や仕事もこなすことができる。このようにして化粧の効用は、心の健康に結びつくのである。

### ③ 化粧によって気分が変化する理由

では、なぜ化粧をすることで気分が変化するのだろうか。これについては、さまざまな立場から説明が試みられている。

社会心理学の立場からは、化粧が「自分の目」と「他者の目」を介して「私はこういう人だ」というアイデンティティの自覚をうながすからだと説明される(菅原、1993)。例えば、化粧によって外見が変化するのを、鏡を介して「自分の目」で観察するとき、「きっとおしゃれで優秀な学生だと思われるだろう」と、まわりが自分に対して抱くであろう印象や期待を想像する。そんな自分への期待に応えようとする動機が高まると、「人に会いたくなる」などの積極性の上昇や「がんば

ろう」といった気持ちにつながる。そして、この外見の変化は「他者の目」に触れることで「すてきな学生さんね」といったまわりの人からの新たな反応を引きだし、自分にフィードバックされる。それによって、自分が期待されている役割を再認識させられるのである。

また、感情心理学の立場からは次のような説明がされている。人は悲しいから泣くのか、泣くから悲しいのか、という議論があるが、鏡に向かって悲しい顔をしていると気分が落ち込み、反対に笑い顔をすると気分が和んでくることを体験した人も多いだろう。気分が好転する化粧の過程をみても、人は、顔を鏡に映して見つめ、顔に触れ、実際に表情を変えてみるという行為を行っている。顔の表情が感情に影響するという顔面フィードバック説からすれば、まさに、化粧を施すことが表情を豊かなものにし、それによって感情が調整され、気分もよくなるというわけである(余語、1996)。

いずれにしても、著名な心理学者マズローが「人間の基本的欲求」の中には「審美的欲求」が含まれていると指摘したように、美しいものを求めるのは理屈ではなく人間の本来の欲求であろう。化粧などの行為により、美しい色彩や香りをまとい、変化する自分を楽しむことによって人間が生来的にもっている欲求を満たし、気分が好転することは確かである。

## ●3 ▶ 高齢者・障害者に対する化粧の心理的効果

では、高齢者や障害者に対する化粧は、どのような効果をもたらすだろうか。 すでに述べたような化粧の効果を、高齢者などが抱える問題に役立てられないか、 という視点から研究されているのが、化粧療法である。

コミュニケーションが困難なこともある認知症高齢者や障害者の場合、一般人を想定した質問紙を使って気分や感情の変化を図ることは難しい。そこで、声の高さ・言葉を発する時間・鏡を見る時間・ほほえむ時間の長さなどの客観的指標の測定や、介護者による行動チェック観察が多く用いられている。

その結果、多くの研究で認められてきた効果は、以下の三点である。

- ① 鏡をよく見るようになるなど、化粧をきっかけに自分への関心が増した
- ② 周囲の人からの声かけに反応が増えたり、自主的に声をかけるようになるなど、社会性や積極性が上昇した
- ③ 病気特有の問題症状が軽減した

ここでは、認知症高齢者に対する化粧療法の研究(伊波ら、1993)を一例とし て紹介しよう。

感情の鈍磨した抑うつ的な(気分が落ち込んだりして、何もできない状態)認

知症高齢者Aさん(82歳)に対して、週1回の頻度で10回の化粧療法を実施し、毎回音声ピッチ(声の高さ)を比較したところ、化粧前よりも終了後に上昇し、覚醒度が高まっていることが示された。そして、鏡を注視する時間も増加して、自分への関心の高まりがみられるとともに、コンパクトをもち歩くようになった。

これらの変化から、ぼんやりしていたAさんの感情がいきいきと活性化したことがうかがえた。反対に、多動や多弁(動き回って5分とじっとしていられない、耳ざわりなほど甲高い声で話す)などの行動の多い認知症高齢者は、回を重ねるごとに長く座り、落ち着きがみられるようになっている。

また、介護者の行動評価のみという点で、データとしての実証性は乏しいが、 化粧プログラムの継続が、表情の変化・自分の容姿への関心の増加・興奮状態の 鎮静化・夜間睡眠剤の廃止・おむつ外しの成功をもたらしたなど、さまざまな問 題症状や行動の軽減が報告されている(土居ら、1994ほか)。

このように、化粧には気分が沈んでしまった認知症高齢者の気分を活性化させる効果が認められ、反対に活性化し過ぎて多動状態になった認知症高齢者には感情を落ち着かせる効果が認められた。これは、化粧が感情調整作用、すなわち「高揚と鎮静」という二面的な心理的効果をもつことの表れである。化粧が一人前の女性であることを示すものであった現在の高齢者にとって、化粧を用いたかかわりは、認知症になる以前のいきいきとした自分を思い出させるものである。それゆえに平板になってしまった気分を高揚させたり、反対に、大人の女性としてふるまおうとして問題行動を減少させる結果となったのだろう。

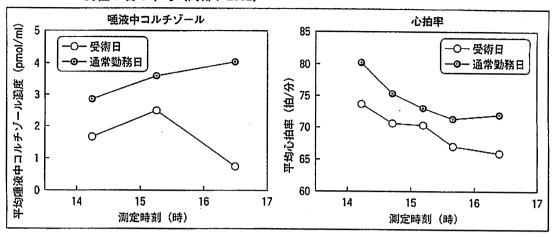
## 4 美容の身体的効果――ストレスの低減

美容の身体的効果は、心拍・脳波・唾液や血液に含まれるストレス指標などを 用いて測定されており、ストレスを低減させることが認められている。もっとも、 そのためにはフェイシャルマッサージやメイクアップに満足していることが必要 である。

## **(1)** スキンケアやエステティックマッサージ

スキンケアやエステティックマッサージによって、ほっとリラックスした気分になることは多い。実際、エステティックマッサージを受けた日は、他の日に比べて、ストレスにより活発化する心拍率(副腎-交感髄質系の活動)や唾液中のコルチゾール濃度(HPA系の活動)が抑制されることがわかった(図1-12)。

●図 1 -12 エステティック受術日と通常勤務日における唾液中コルチゾール濃度と心拍率 男性 3 名の平均(阿部、2002)



## **@2D** メイクアップ

化粧にも、抗ストレス効果が認められている。例えば、宇野(1998)は、脳血管疾患・心疾患・パーキンソン病などで長期入院をしている高齢の患者に対して、月1回の美容専門家による化粧療法と毎日の化粧を組み合わせて行い、5か月間の変化を測定した。その結果、血中の免疫指標(インターフェロンα産性能およびナチュラルキラー活性)に増加がみられ、行動面でも自発性・積極性・表情の改善・食欲や睡眠の改善も認められた。このような高齢者の免疫機能の増大は、感染に対する抵抗力のアップにもつながるのではないかと期待されている。

## 5 美容福祉の実践

#### @10 化粧を用いる理由

高齢者や障害者の気分や感情を活性化させるには、音楽や回想などさまざまな 方法があるが、あえて化粧を用いるメリットは、以下の点である(伊波、2001)。

- ① 受け入れやすい:刺激が日常的なものなので、心理的な違和感は比較的少ない
- ② 味覚以外がすべて刺激される: 五感に訴える手がかりが豊富である
- ③ 実施が簡単:道具の入手および実施が比較的簡便であり、作業負担が軽い
- ④ 変化がわかりやすく、対人交流に結びつきやすい:実施前後あるいはその過程における変化が視覚的に明らかなため、施術実感を得やすく、対人的なやり

とりを活性化させられる

⑤ 継続が可能である:プログラム終了後、参加者が自発的、日常的かつ習慣的 に化粧を取り入れることも可能である

## (2) 美容福祉の効果

自信や満足感が上昇するといった化粧の心理的・身体的効果は、個人で化粧を した場合にも少なからず生じるものである。さらに、私たちが現場で美容福祉を 実践する場合、人との交流が生じることによる効果がある。例えば、担当した美 容専門家とのやりとりやプログラム終了後の介護職やほかの入居者の反応など が、場合によっては化粧そのものよりも、心理的・身体的効果に大きく影響する。 なぜなら、人は他者に受容されてはじめて、自分を大切に思うことができる(自 尊感情が上昇する)からである。

美容福祉の実施にあたり、おしゃれを楽しむ姿をともに喜び、「きれいね、素敵な人ね」などとポジティブな反応をかえすこと、一人の尊敬すべき大切な人として、高齢者や障害者に心から接することは、対象者の自尊感情を高め、ひいては精神的健康や社会的適応を促進するのに不可欠である。

美容福祉の効果 = 美容の効果 + 対人交流の効果

#### (3) 美容福祉と介護予防

美容福祉は、2005 (平成17) 年の介護保険法の改正によりクローズアップされた「介護予防」にも役立つ。介護予防の意義は、①要介護状態の方の状態悪化を防ぐだけでなく、②一般高齢者が要支援・要介護状態になることをできるだけ防ぐことにある。このうち、①の要介護状態の方への化粧プログラムについては、さまざまな研究がなされ、その有効性が認められている。

今後は、②の一般高齢者に対する介護予防としての美容福祉にも積極的に取り組むことが必要である。例えば、一般高齢者の介護予防を制度化した地域支援事業においては、うつ・閉じこもり・認知症の予防に重点が置かれている。そのような地域支援事業の一つとして一般高齢者に対して楽しく安全な美容プログラムを実施することができれば、彼らの心身を活性化して社会参加を促進するだけでなく、その五感が刺激されることにより認知症の予防にもなると思われる。

## 6 おわりに

高齢になっても、病気や障害があっても、その人らしく人生を楽しみながら生きることは、人間に認められた権利のはずである。だとすれば、その人の尊厳を保つために化粧や装いといったことも、できるかぎり尊重されることが望ましい。しかし、現実はなかなか厳しく、職員数の限られた施設では「申し訳ありませんが、手がまわらないのでお化粧は落として帰ってくださいね」と声をかけられることがある。

筆者は以前、パリにある重度認知症患者の多い公立老人病院を訪問し、そこで 美容ケアをしていた美容専門家に、ここではそのようなことを注意されないのか 質問したことがある。すると彼女たちはとても不思議そうな顔で筆者を見た後、 こういった。

「どうして時間の限られている人に、そんなことが許されないのですか?」

予想外の反対質問に、恥ずかしさで返す言葉を失った。日本で施設側の注意に どこか納得していた筆者は、何のため、誰のためにそのような活動をしていたの だろうかと反省させられた。

美容福祉を推進することは、少しぐらいシーツが汚れても、その人が楽しく過ごせることを優先して認められる雰囲気を、社会に広げていくことであろう。

#### ORIGINAL PAPER

## A retrospective study of the impact of age on patterns of care for elderly patients with metastatic breast cancer

Kenji Hashimoto · Kan Yonemori · Chikako Shimizu · Akihiro Hirakawa · Harukaze Yamamoto · Makiko Ono · Taizo Hirata · Tsutomu Kouno · Kenji Tamura · Noriyuki Katsumata · Masashi Ando · Yasuhiro Fujiwara

Received: 9 March 2010/Accepted: 11 March 2010 © Springer Science+Business Media, LLC 2010

**Abstract** This study aims at evaluating the impact of age on patterns of care in elderly patients with metastatic breast cancer (MBC) and their outcome. We identified 177 patients aged ≥65 treated for MBC at the National Cancer Center Hospital in Japan from 1999 to 2007. We evaluated the impact of age on the selection of best supportive care (BSC) only, chemotherapy as first-line treatment, and chemotherapy after first-line endocrine therapy. Fisher's exact test and a multivariate logistic regression analysis with variables of age, performance status (PS), hormone receptor (HR) status, human epidermal growth factor-2 (HER2), and life-threatening disease (LTD) were used. The median age of patients was 72, and 60 patients (33.9%) were aged ≥75. HR-negative patients and those whose PS was  $\geq 2$ , regardless of age, were more likely to choose BSC without chemotherapy. Multivariate analysis revealed age  $\geq 75$  (P = 0.018), positive-HR status (P < 0.001), and absence of LTD (P < 0.001) were significantly correlated to choose endocrine therapy rather than chemotherapy. In patients who had previous endocrine therapy, age (P = 0.008) and absence of HER2 (P = 0.018) were

This study was presented as a part of 10th annual meeting of the International Society of Geriatric Oncology (ISGO), October 15-17, 2009, Berlin, Germany.

K. Hashimoto ⋅ K. Yonemori (⋈) ⋅ C. Shimizu ⋅ H. Yamamoto · M. Ono · T. Hirata · T. Kouno · K. Tamura · N. Katsumata · M. Ando · Y. Fujiwara Breast and Medical Oncology Division, National Cancer Center Hospital, 5-1-1 Tsukiji, Chuo-ku, Tokyo 104-0045, Japan e-mail: kyonemor@ncc.go.jp

#### A. Hirakawa

Department of Management Science, Graduate School of Engineering, Tokyo University of Science, Shinjuku-ku, Tokyo 162-8601, Japan

related not to choose chemotherapy. Not age but HRnegative status or  $PS \ge 2$  were related to the selection of BSC. In selecting endocrine therapy rather than chemotherapy, age ( $\geq$ 75), HR-positive, and absence of LTD were significant factors. In patients failed to endocrine therapy, age and HER2 status were correlated to decision-making to choose chemotherapy.

Keywords Metastatic breast cancer · Patterns of care · Elderly · Age · Chemotherapy

#### Introduction

Health care for elderly patients has arisen as an urgent public health issue in industrialized countries, including Japan. Elderly patients with advanced breast cancer are not often managed according to treatment guidelines, since a standard of care for the elderly has not yet been established [1]. The treatment of elderly patients, therefore, is generally modified to account for considerations of age and the subjective evaluation of the patient's general status [2].

Comprehensive geriatric assessment other than performance status (PS) should be carried out when physicians select a treatment for patients with cancer [3-6]. When treating elderly patients with cancer, especially with chemotherapy, oncologists should pay careful attention to the treatment procedure and consider dose modification depending on the drugs [7].

Some reports suggest that elderly patients with breast cancer are less likely to receive breast conservation surgery, radiation, and chemotherapy [8-16]. These may indicate both patient and physician preferences toward avoiding cytotoxic agents [10]. Although the use of surgery, endocrine therapy, and chemotherapy has been monitored, there

💥 Humana Press

Published online: 31 March 2010

are little data available on the relationship between treatment selection, particularly cytotoxic chemotherapy, and outcome in elderly patients with metastatic breast cancer. In this study, we evaluated the impact of age together with other factors on patterns of care in elderly patients with metastatic breast cancer. Safety and efficacy were also evaluated in patients who received chemotherapy as first-line treatment.

#### Methods

#### Study population

Patients aged 65 or older treated for metastatic breast cancer between January 1999 and December 2007 were identified from the database of the National Cancer Center Hospital (NCCH) in Japan. Patient eligibility criteria were as follows: (1) histologically or cytologically proven breast cancer,  $(2) \ge 65$  years of age at diagnosis, (3) metastatic breast cancer including distant recurrence after surgery, and (4) no previous treatment for metastatic disease at the time of the first consultation at the NCCH. Medical charts of all the eligible patients were reviewed, and the following data were collected for analysis: age, height, weight, performance status (PS), hormone receptor (HR) status, human epidermal receptor type 2 (HER2) status, life-threatening disease (LTD) status due to breast cancer, comorbidity, medication, laboratory data, living alone or with family, distance from our hospital, chemotherapy regimen, and endocrine therapy regimen. Creatinine clearance (Ccr) was calculated using Cockcroft-Gault;  $Ccr = (140 - age) \times$ body weight/72  $\times$  creatinine ( $\times 0.85$  for woman).

The HR status was considered to be positive either estrogen receptor or progesterone receptor presented. The HER2 status was considered to be positive if an immuno-histochemical staining intensity of 3+ or fluorescence in situ hybridization signal ratio > 2.2 was observed. LTD was defined as the presence of dyspnea due to metastasis or pleural effusion, sub-clinical ileus due to peritoneal metastasis, multiple liver metastases, or some other critical symptom due to breast cancer.

This study was approved by the institutional review board at the National Cancer Center Hospital, Tokyo.

General recommendations for metastatic breast cancer at the NCCH and actual treatment of the elderly

Aromatase inhibitor was used as the first-line endocrine treatment for HR-positive breast cancer patients without LTD. Tamoxifen can be a substitute for the patients with the risk of osteoporosis. HR-positive patients with LTD generally receive chemotherapy as the first-line treatment.

HR-negative patients generally receive chemotherapy with or without trastuzumab, depending on HER2 status. Chemotherapy regimens generally started with anthracycline (40 mg/m²) and cyclophosphamide (500 mg/m²) every 3 weeks or with weekly administration of paclitaxel (80 mg/m²). Capecitabine (2,500 mg/m²) for 2 weeks following 1 week of rest can be used after failure of anthracycline and taxane. For patients who had previously undergone adjuvant or neoadjuvant chemotherapy, capecitabine or taxane re-challenge is recommended.

#### Statistical analysis

We evaluated the impact of age on the selection of (1) best supportive care (BSC) only, (2) chemotherapy as first-line treatment, or (3) chemotherapy after first-line endocrine therapy, together with PS, HR status, HER2 status, and LTD status.

We first compared the age of the patients who received only BSC with those who received additional treatments. Next, excluding patients with BSC, we compared the age of patients who received chemotherapy with those who received endocrine therapy as the first-line treatment. Finally, among the patients who received endocrine therapy as the first-line treatment, we compared age between the patients who received at least one chemotherapy regimen throughout the disease course and those who did not.

In these analyses, the impact of age was evaluated using Fisher's exact test and multivariate logistic regression analysis. PS  $(0-1 \text{ vs.} \ge 2)$ , HR status (negative vs. positive), HER2 status (negative vs. positive), and LTD status (no vs. yes) were included in the multivariate logistic model. Age was categorized into three groups: 65-69 years, 70-74 years, and  $\ge 75 \text{ years}$ .

Additionally, for the patients who received chemotherapy as a first-line treatment, the toxicity of each chemotherapy regimen, response rate, number of cycles, and the proportion of doses subjected to modification were summarized. Overall survival was defined as the time from first-line treatment to death due to any cause or the date of the last visit for patients for whom no death was recorded. It should be noted that the start date of overall survival for patients treated only with BSC was defined as the date of the determination to proceed with BSC. The Kaplan-Meier method was used to estimate the median survival time (MST). A two-sided  $P \le 0.05$  was considered to be statistically significant. Tumor response was evaluated according to WHO criteria by the investigators. All adverse events were ranked according to Common Toxicity Criteria for Adverse Events (CTC-AE) version 3.0. All analyses were conducted using SAS (version 9.1, SAS Institute Inc., Cary, NC, USA).

#### # Humana Press

**Table 1** Patient characteristics (N = 177)

	N (%)
Age	
Median (range)	72 (66–86)
65–69	58 (32.8)
70–74	59 (33.3)
≥75	60 (33.9)
Height (cm)	
Median (range)	151 (134–171)
Weight (kg)	
Median (range)	50 (31–83)
PS	
0	67 (37.9)
1	89 (50.3)
2	14 (7.9)
3	6 (3.4)
4	1 (0.6)
Laboratory data at diagnosis	- ()
Serum albumin (g/dl) (normal range 3.7–5.2)	4.0 (2.1–5.0)
Serum AST (IU/L) (normal range 13–33)	24 (14.0–223.0)
Serum ALT (IU/L) (normal range 8–42)	17 (6.0–483.0)
	0.6 (0.3–1.2)
Serum creatinine (mg/dL) (normal range 0.4–0.7)	0.0 (0.5-1.2)
Creatinine clearance (mL/minutes)	65.3 (27.8–117.8)
Hemoglobin (g/dL) (normal range 13.7–17.4)	12.7 (8.2–15.6)
HR status	
Negative	57 (32.2)
Positive	120 (67.8)
HER2 status	
Negative	149 (84.2)
Positive	28 (15.8)
LTD status	
No	153 (86.4)
Yes	24 (13.6)
Number of metastases	
0–1	102 (57.6)
≥2	75 (42.4)
Number of comorbidities	
0	56 (31.6)
1	47 (26.6)
>2	74 (41.8)
Comorbidities	, ,
Hypertension	67 (37.9)
Diabetes	25 (14.1)
Respiratory disease	24 (13.6)
Cardiovascular disease	19 (10.7)
Number of medications for comorbidity	(-011)
•	1 (0–11)
Median (range)	1 (0-11)

Table 1 continued

	N (%)
Living alone or with family	
Alone	17 (9.6)
With family	160 (90.4)
Distance from hospital (km)	
<100	158 (89.3)
≥100	19 (10.7)
First-line treatment	
BSC	5 (2.8)
Hormone therapy	104 (58.8)
Chemotherapy	68 (38.4)

Figures in parentheses are percentages of patients except for median age, height, and weight

PS performance status, AST aspartate aminotransferase, ALT alanine aminotransferase, HR hormone receptor, HER2 human epidermal receptor type 2, LTD life-threatening disease, BSC best supportive care

#### Results

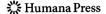
#### Patient characteristics

We identified 177 elderly patients with metastatic breast cancer. Patient characteristics are summarized in Table 1. Median age was 72, and nearly 90% of the patients were PS 0 or 1. Approximately, 68% of patients had one or more comorbidities such as hypertension, diabetes, or respiratory disease. Median survival time of all patients was 36.9 months (range 0.36–126.9 months). Of the 177 patients, 103 had died. Of these, 95 patients (92.2%) died of primary cancer, and the others died due to comorbidities. No patients died due to adverse effects of treatment.

Seven of 68 patients (10.3%) received non-standard chemotherapy as defined by our division, including capecitabine or vinorelbine. Trastuzumab monotherapy was used as the first-line treatment in an additional 8 of 68 patients (11.8%). Response rate, number of cycles, and dose modifications for each first-line treatment regimen of endocrine therapy and chemotherapy are shown in Table 2. For patients who received first-line chemotherapy treatment, the response rate was 50%, and dose was mainly adjusted on the basis of liver function or the occurrence of febrile neutropenia in a prior course.

Impact of age on the selection of BSC

Five patients received only BSC. Their characteristics are contrasted with those of the other 172 patients in Table 3. Fisher's exact tests for differences in PS and HR status



**Table 2** Response, number of cycles, and dose modifications for each regimen of chemotherapy and hormone therapy

	N	Response N (%)	Median number of cycles (range)	Dose modification <i>N</i> (%)
Endocrine therapy	104	24 (23.1)		
Aromatase inhibitors	80	21 (26.3)	_	_
Tamoxifen	24	3 (12.5)	_	_
Chemotherapy	68	34 (50.0)	6 (1–42)	8 (11.8)
Anthracyclines	24	12 (50.0)	6 (1–10)	1 (4.2)
Taxanes	29	18 (62.1)	5 (1–18)	5 (17.2)
Trastuzumab alone	8	1 (12.5)	6 (2–42)	0 (0.0)
Others	7	3 (42.9)	6 (1–12)	2 (28.6)

Table 3 Comparison of characteristics of patients treated with BSC only with others

	BSC (N = 5)	Others $(N = 172)$	P value*
Age			0.621
65-69	1 (20.0)	57 (33.1)	
70–74	1 (20.0)	58 (33.7)	
≥75	3 (60.0)	57 (33.1)	
PS			< 0.001
0-1	1 (20.0)	155 (90.1)	
≥2	4 (80.0)	17 (9.9)	
HR status			0.003
Negative	5 (100.0)	52 (30.2)	
Positive	0 (0.0)	120 (69.8)	
HER2 status			0.582
Negative	4 (80.0)	145 (84.3)	
Positive	1 (20.0)	27 (15.7)	
LTD status			0.522
No	4 (80.0)	149 (86.6)	
Yes	1 (20.0)	23 (13.4)	

Figures in parentheses are percentages of patients

PS performance status, HR hormone receptor, HER2 human epidermal receptor type 2, LTD life-threatening disease

were statistically significant (P < 0.001 and P = 0.003, respectively). Additionally, according to the results of multivariate logistic regression analysis, the odds ratio (OR) of treatment with BSC in the groups aged 70–74 and  $\geq$ 75 in comparison with the group aged 65–69 were 1.17 (P = 1.00) and 5.11 (P = 0.426), respectively. In contrast, the ORs of PS and HR status were 36.2 (P = 0.005) and 0.07 (P = 0.014), respectively. These results indicate that patients with HR-negative status or PS  $\geq$  2 were more likely to choose BSC only and that age was not a significant factor in that decision. The MST of the 5 patients with BSC was 6.2 months (range 1.1–22.3 months), while that of the other 172 patients was 36.9 months (range 0.4–96.4 months).

Impact of age on the selection of chemotherapy as first-line treatment

Among the 172 patients who received additional treatment, 68 and 104 patients received chemotherapy and endocrine therapy, respectively, as first-line treatment. Patient characteristics in the two treatment groups are listed in Table 4. Age, PS, HR status, HER2 status, and LTD status were significantly different between the groups. In the multivariate logistic regression analysis, ORs for receiving chemotherapy in the groups aged 70-74 and  $\geq$ 75 compared to the group aged 65-69 were 0.21 (P = 0.157) and 0.03 (P = 0.018), respectively. The ORs for PS, HR status, HER2, and LTD were 4.98 (P = 0.517), <0.01 (P < 0.001), 12.04 (P = 0.082), and 64.18 (P < 0.001), respectively. These results indicate that patients  $\geq 75$  years, HR-positive, or with an absence of LTD tended to avoid chemotherapy. The MST of 68 patients treated with chemotherapy was 25.4 months (range 0.4-126.9 months), while that of 104 patients treated with hormone therapy was 48.5 months (range 3.0-122.0 months). Toxicity profiles for chemotherapy are summarized in Table 5. Grade 3/4 neutropenia was observed in each regimen (24% for anthracyclines and 10.3% for taxanes), but febrile neutropenia was less common. None developed cardiotoxicity, and no treatmentrelated deaths were observed.

Impact of age on the selection of chemotherapy after first-line endocrine therapy

We further evaluated the impact of age on the selection of at least one chemotherapy regimen after first-line treatment. Among 104 patients who received hormone therapy as first-line treatment, 50 patients are still undergoing follow-up as of May 2009. Because these patients have the possibility of receiving chemotherapy until death, we evaluated the impact of age in the 54 patients who died. Of these, 27 patients received at least one chemotherapy regimen after failure of first-line endocrine therapy, and 27 patients did not. Patient characteristics of the two groups

#### Humana Press

<sup>\*</sup> Fisher exact test

Table 4 Comparison of characteristics of patients who received endocrine therapy and chemotherapy as first-line treatment

	Endocrine therapy $(N = 104)$	Chemotherapy $(N = 68)$	P value*
Age			0.009
65–69	26 (25.0)	31 (45.6)	
70–74	36 (34.6)	22 (32.4)	
≥75	42 (40.4)	15 (22.1)	
PS			0.036
0-1	98 (94.2)	57 (83.8)	
≥2	6 (5.8)	11 (16.2)	
HR status			< 0.001
Negative	0 (0.0)	52 (76.5)	
Positive	104 (100)	16 (23.5)	
HER2 status			< 0.001
Negative	97 (93.3)	48 (70.6)	
Positive	7 (6.7)	20 (29.4)	
LTD status			< 0.001
No	101 (97.1)	48 (70.6)	
Yes	3 (2.9)	20 (29.4)	

Figures in parentheses are percentages of patients

PS performance status, HR hormone receptor, HER2 human epidermal receptor type 2, LTD life-threatening disease

are summarized in Table 6. Age distribution was significantly different between the two groups (P=0.021), while the other covariates were not. In the multivariate logistic regression analysis, ORs for undergoing chemotherapy in the groups aged 70–74 and  $\geq$ 75 in comparison with the group aged 65–69 were 0.55 (P=0.642) and 0.08 (P=0.008), respectively, while the ORs for PS, HER2, and LTD were 0.41 (P=0.895), 15.43 (P=0.018), and 0.38 (P=1.000), respectively. These results indicate that age and HER2 status were factors in the decision to receive

chemotherapy among HR-positive patients. The MST of patients who received at least one chemotherapy regimen and those who did not were 22.8 months (range 3.1–73.8 months) and 15.2 months (range 3.0–77.3 months), respectively.

#### Discussion

We analyzed patterns of care in elderly patients with metastatic breast cancer and the impact of age on treatment choice. The present study results indicate that PS and HR status rather than age were significantly associated with the selection of BSC. With regard to the selection of chemotherapy, age was an independent factor affecting patterns of care. In particular, patients aged ≥75 tended not to receive chemotherapy throughout the treatment course, compared with those aged <75. Age was a strong factor in the decision to receive chemotherapy, especially in HR-positive patients. We further evaluated the impact of comorbidities, number of internal medicines, presence of family, and distance from hospital on the patterns of care, which were not related to the treatment pattern (data not shown).

In this analysis, only 5 patients received BSC without additional treatment, and their age was not identified as a factor affecting patterns of care. We previously reported that young patients with breast cancer tended to receive palliative chemotherapy within 90 days of death even with PS > 2 [17]. Considering this finding, elderly patients were less aggressive in their preference for chemotherapy than the young. Three HR-positive patients with LTD in our cohort underwent endocrine therapy. Endocrine therapies might be prescribed more frequently than chemotherapy for elderly patients even in patients with a lower expected response.

The International Society of Geriatric Oncology recommends that HR-negative breast cancer patients over

Table 5 Toxicity of each chemotherapy regimen in patients with first-line chemotherapy treatment

Grade	Anthracyclines $(N = 24)$		Taxanes $(N = 29)$		Others $(N = 15)$	
	Any N (%)	3/4 N (%)	Any N (%)	3/4 N (%)	Any N (%)	3/4 N (%)
Leukocyte	7 (29.2)	3 (12.5)	11 (37.9)	3 (10.3)	2 (13.3)	0 (0.0)
Neutrophil	9 (37.5)	6 (24.0)	12 (41.4)	3 (10.3)	3 (20.0)	1 (6.7)
Hemoglobin	3 (12.5)	0 (0.0)	6 (20.7)	2 (6.9)	1 (6.7)	0 (0.0)
Platelet	2 (8.3)	0 (0.0)	1 (3.5)	1 (3.5)	2 (13.3)	0 (0.0)
Febrile neutropenia	_	2 (8.4)	_	2 (6.9)		1 (6.7)
Diarrhea	0 (0.0)	0 (0.0)	6 (20.7)	2 (6.9)	1 (6.7)	0 (0.0)
Nausea	11 (45.8)	0 (0.0)	14 (48.3)	0 (0.0)	1 (6.7)	0 (0.0)
Vomiting	4 (16.7)	0 (0.0)	3 (10.7)	0 (0.0)	0 (0.0)	0 (0.0)
Neuropathy	0 (0.0)	0 (0.0)	20 (69.0)	1 (3.5)	3 (20.0)	1 (6.7)
Alopecia	15 (62.5)	_	16 (55.2)		3 (20.0)	_

**# Humana Press** 

<sup>\*</sup> Fisher exact test

Table 6 Comparison of patient characteristics in patients with or without chemotherapy after first-line endocrine therapy

Variables	Non-chemotherapy	Chamatharan	P value*	
- unables	(N = 27)	Chemotherapy $(N = 27)$		
Age				
65-69	4 (14.8)	10 (37.0)	0.021	
70-74	9 (33.3)	12 (44.4)		
≥75	14 (51.9)	5 (18.5)		
PS				
0-1	23 (85.2)	26 (96.3)	0.351	
≥2	4 (14.8)	1 (3.7)		
HR status			NE	
Negative	0 (0.0)	0 (0.0)		
Positive	27 (100.0)	27 (100.0)		
HER2				
Negative	27 (100.0)	23 (85.2)	0.111	
Positive	0 (0.0)	4 (14.8)		
LTD status				
No	27 (100.0)	26 (96.3)	1.000	
Yes	0 (0.0)	1 (3.7)		

Figures in parentheses are percentages of patients

PS performance status, HR hormone receptor, HER2 human epidermal receptor type 2, LTD life-threatening disease, NE not evaluated

\* Fisher exact test

70 years of age should not be excluded from receiving chemotherapy [1]. Although it is important to focus on the survival benefit of chemotherapy for breast cancer, estimating the benefit of chemotherapy simply by survival or disease-free interval may not be appropriate for elderly patients because their life expectancy is limited and chemotherapy may disturb their activities of daily living (ADL). Because of the retrospective nature of analysis, ADL and instrumental ADL (IADL) were not evaluated. In elderly patients, a worldwide consensus has not been established for the evaluation of ADL in chemotherapy, although a validated multidimensional evaluation scale exists [18]. ADL and other comprehensive geriatric assessments should be carried out when starting chemotherapy to add more information to PS [19]. In Japan, women average length of life is 86 in 2009, and the most common causes of death are cancer, cardiovascular events and cerebrovascular events. Elderly patients with vascular events or aged 80 should avoid the treatments which disturb ADL or IADL.

Freyer et al. reported the pattern of treatment in patients with metastatic breast cancer in France whose age  $\geq 65$ . They reported selection of BSC was not affected by the age  $(65-74 \text{ vs. } \geq 75)$  and selection of endocrine therapy rather than chemotherapy was significantly affected by age, as we revealed [2]. Hamberg et al. summarized response rate of

chemotherapy in patients with metastatic breast cancer aged  $\geq$ 65 [20]. This study showed similar results to those summarized by them as for response rate (50%) and tolerable toxicity profile for patients who received first-line treatment with chemotherapy, although the number of patients aged  $\geq$  75 was limited.

This study has some limitations because of its retrospective nature. We could not rank the patients according to comprehensive geriatric assessment because of lack of information by chart review. We could not identify the reasons whether less aggressiveness for the treatment in elderly patients is due to patients' preference or physicians' preference. There may be selection bias for patients who received chemotherapy because of the nature of our hospital. Furthermore, the safety and efficacy of chemotherapy could not be evaluated in the manner of phase II/III trials, and the regimens used were skewed. Response rate may be overestimated due to this bias. Methodology for scoring comorbidities, medications, and sociocultural differences should be developed for future studies. However, our results still provide valuable information for oncologists.

In conclusion, we evaluated the impact of age on patterns of care in elderly patients with breast cancer and the outcomes of patients who received chemotherapy as the first-line treatment. Not age but HR-negative status or  $PS \geq 2$  were more related to the selection of BSC. In selecting endocrine therapy rather than chemotherapy, age ( $\geq 75$ ), HR-positive, and absence of LTD were significant factors. In patients' failure to endocrine therapy, age and HER2 status were correlated to decision-making to choose chemotherapy.

**Acknowledgments** We thank Ms. Ikuko Takeda (secretary) and Ms. Nao Nakamura (secretary) for helping with data collection and manuscript corrections.

Conflicts of interest statement None.

#### References

- Wildiers H, Kunkler I, Biganzoli L, et al. Management of breast cancer in elderly individuals: recommendations of the International Society of Geriatric Oncology. Lancet Oncol. 2007;8: 1101–15.
- Freyer G, Braud AC, Chaibi P, et al. Dealing with metastatic breast cancer in elderly women: results from a French study on a large cohort carried out by the 'Observatory on Elderly Patients'. Ann Oncol. 2006;17:211–6.
- Freyer G, Geay JF, Touzet S, et al. Comprehensive geriatric assessment predicts tolerance to chemotherapy and survival in elderly patients with advanced ovarian carcinoma: a GINECO study. Ann Oncol. 2005;16:1795–800.
- Pentheroudakis G, Fountzilas G, Kalofonos HP, et al. Palliative chemotherapy in elderly patients with common metastatic malignancies: a Hellenic Cooperative Oncology Group registry

#### Humana Press

- analysis of management, outcome and clinical benefit predictors. Crit Rev Oncol Hematol. 2008;66:237–47.
- Maas HA, Janssen-Heijnen ML, Olde Rikkert MG, Machteld Wymenga AN. Comprehensive geriatric assessment and its clinical impact in oncology. Eur J Cancer. 2007;43:2161–9.
- Extermann M, Hurria A. Comprehensive geriatric assessment for older patients with cancer. J Clin Oncol. 2007;25:1824–31.
- Lichtman SM, Wildiers H, Chatelut E, et al. International Society of Geriatric Oncology Chemotherapy Taskforce: evaluation of chemotherapy in older patients—an analysis of the medical literature. J Clin Oncol. 2007;25:1832–43.
- Greenfield S, Blanco DM, Elashoff RM, Ganz PA. Patterns of care related to age of breast cancer patients. JAMA. 1987;257: 2766-70.
- Samet JM, Hunt WC, Farrow DC. Determinants of receiving breast-conserving surgery. The surveillance, epidemiology, and end results program, 1983–1986. Cancer. 1994;73:2344–51.
- Mandelblatt JS, Hadley J, Kerner JF, et al. Patterns of breast carcinoma treatment in older women: patient preference and clinical and physical influences. Cancer. 2000;89:561-73.
- Newcomb PA, Carbone PP. Cancer treatment and age: patient perspectives. J Natl Cancer Inst. 1993;85:1580–4.
- 12. Bergman L, Dekker G, van Leeuwen FE, et al. The effect of age on treatment choice and survival in elderly breast cancer patients. Cancer. 1991;67:2227–34.
- 13. Bergman L, Kluck HM, van Leeuwen FE, et al. The influence of age on treatment choice and survival of elderly breast cancer

- patients in south-eastern Netherlands: a population-based study. Eur J Cancer. 1992;28A:1475–80.
- Christman K, Muss HB, Case LD, Stanley V. Chemotherapy of metastatic breast cancer in the elderly. The Piedmont Oncology Association experience [see comment]. JAMA. 1992;268:57–62.
- Bergman L, Dekker G, van Kerkhoff EH, et al. Influence of age and comorbidity on treatment choice and survival in elderly patients with breast cancer. Breast Cancer Res Treat. 1991;18: 189–98.
- Hurria A, Leung D, Trainor K, et al. Factors influencing treatment patterns of breast cancer patients age 75 and older. Crit Rev Oncol Hematol. 2003;46:121-6.
- Hashimoto K, Yonemori K, Katsumata N, et al. Factors that affect the duration of the interval between the completion of palliative chemotherapy and death. Oncologist. 2009;14:752–9.
- Monfardini S, Ferrucci L, Fratino L, et al. Validation of a multidimensional evaluation scale for use in elderly cancer patients. Cancer. 1996;77:395–401.
- Repetto L, Fratino L, Audisio RA, et al. Comprehensive geriatric assessment adds information to Eastern Cooperative Oncology Group performance status in elderly cancer patients: an Italian Group for Geriatric Oncology Study. J Clin Oncol. 2002;20:494– 502.
- Hamberg P, Verweij J, Seynaeve C. Cytotoxic therapy for the elderly with metastatic breast cancer: a review on safety, pharmacokinetics and efficacy. Eur J Cancer. 2007;43:1514–28.

# Feasibility and usefulness of the 'Distress Screening Program in Ambulatory Care' in clinical oncology practice<sup>†</sup>

Ken Shimizu<sup>1,2</sup>, Yuki Ishibashi<sup>1</sup>, Shino Umezawa<sup>3</sup>, Hideko Izumi<sup>3</sup>, Nobuya Akizuki<sup>2,4</sup>, Asao Ogawa<sup>2,4</sup>, Yasuhiro Fujiwara<sup>5</sup>, Masashi Ando<sup>5</sup>, Noriyuki Katsumata<sup>5</sup>, Kenji Tamura<sup>5</sup>, Tsutomu Kouno<sup>5‡</sup>, Chikako Shimizu<sup>5</sup>, Kan Yonemori<sup>5</sup>, Mayu Yunokawa<sup>5</sup> and Yosuke Uchitomi<sup>2,4\*</sup>

\*Correspondence to: Psycho-Oncology Division, Research Center for Innovative Oncology, National Cancer Center Hospital East, 6-5-1 Kashiwanoha, Kashiwa, Chiba 277-8577, Japan. E-mail:

yuchitom@east.ncc.go.jp

†This article was published
online on 11 August 2009.
An error was subsequently
identified. This notice is
included in the online and
print versions to indicate that
both have been corrected
[11/11/09].

<sup>‡</sup>[Correction made here after initial online publication].

Received: 11 February 2009 Revised: 17 May 2009 Accepted: 28 June 2009

#### **Abstract**

Objective: Although the implementation of routine screening for distress is desirable, doing so is difficult in today's busy clinical oncology practice. We developed the 'Distress Screening Program in Ambulatory Care' (DISPAC program) as a practical means of screening for and facilitating the treatment of major depression and adjustment disorders in cancer patients. This study assessed the feasibility and usefulness of the DISPAC program in actual clinical situations.

Methods: As part of the DISPAC program, nurses administered a psychological screening measure, the Distress and Impact Thermometer (DIT), to consecutive cancer patients visiting an outpatient clinic in the waiting room. The attending physician then recommended psychoncology service referral to all positively screened patients. We compared the proportion of patients referred to a psycho-oncology service during the DISPAC period with the usual care period.

Results: Of the targeted 491 patients treated during the DISPAC period, 91.9% (451/491) completed the DIT; the results were positive in 37.0% (167/451), recommendations for referrals were given to 93.4% (156/167), and 25.0% (39/156) accepted the referral. Ultimately 5.3% (26/491) of the targeted patients were treated by psycho-oncology service as having major depression or adjustment disorders, a significantly higher proportion than during the usual care period (0.3%; p < 0.001). The nurses required 132 $\pm$ 58 s per person to administer the DIT.

Conclusions: The DISPAC program is useful for facilitating the care of cancer patients with psychological distress. Nevertheless, the acceptance of referrals by patients and the reduction of the burden placed on nurses are areas requiring improvement. Copyright © 2009 John Wiley & Sons, Ltd.

Keywords: screening; cancer; oncology; distress; depression

#### Introduction

As cancer is a life-threatening illness, patients may experience strong psychological distress and frequently develop psychiatric disorders such as major depression or adjustment disorders [1]. The prevalence of major depression has been reported to be 3–26%, and the prevalence of adjustment disorders in patients with cancer has been reported to be 4–35% [1–8]. Major depression and adjustment disorders have a negative impact on quality of life [9], patient decision-making regarding cancer treatment [10], the length of the hospital stay [11],

patient suicide [12], and caregiver distress [13]. Since evidence suggests that psychotherapy [14] and pharmacotherapy [15] are effective means of treating these disorders, these treatments should be provided when necessary. Psychological distress, however, is often under-recognized by medical staff members, including oncologists and oncology nurses, in clinical oncology settings [16–18].

Screening is the optimal strategy for detecting diseases (such as major depression and adjustment disorders) that are prevalent, not evident, and treatable and that benefit from early treatment [19]. For physically healthy patients with major

Psycho-Oncology Division, National Cancer Center Hospital, Chuou-ku, Tokyo, Japan

<sup>&</sup>lt;sup>2</sup>Psycho-Oncology Division, Research Center for Innovative Oncology, National Cancer Center Hospital East, Kashiwa, Chiba, Japan

<sup>&</sup>lt;sup>3</sup>Nursing Division, National Cancer Center Hospital, Chuou-ku, Tokyo, Japan

<sup>&</sup>lt;sup>4</sup>Psycho-Oncology Division, National Cancer Center Hospital East, Kashiwa, Chiba, Japan

 $<sup>^5</sup>$ Breast and Medical Oncology Division, National Cancer Center Hospital, Chuou-ku, Tokyo, Japan

depression, programs that combine psychological screening and adequate collaboration with mental health specialists have been shown to improve psychological symptoms and general functioning [20]. In oncology settings, although less empirical evidence is available than for physically healthy patients, a high risk of depressive disorders has been reported [6], and psychological screening has been shown to be capable of detecting depressive disorders in cancer patients [21,22]; furthermore, psychological interventions have been shown to alleviate depressive disorders detected by psychological screening [23,24]. This evidence supports the efficacy of psychological screening for cancer patients, and guidelines such as the National Comprehensive Cancer Network and the National Institute for Clinical Excellence have recommended routine screening for depressive disorders in clinical practice. However, a limited number of institutions have introduced such programs because of insufficient resources [25], and a practical program that can be implemented in busy clinical settings with limited resources is needed.

Our group has spent several years developing a practical psychological screening program for cancer patients. First, we developed and validated some distress-screening tools [26–28]. Among them, the Distress and Impact Thermometer (DIT), which was developed by modifying the Distress Thermometer [21,27], has shown a high performance and is brief enough to use in busy clinical settings [28]. We next developed and introduced a distress screening and psychiatric referral program as part of a clinical screening protocol targeting hospitalized patients. The feasibility and usefulness of this program has been reported elsewhere [29,30].

Recently, oncology treatment has undergone major changes, and many patients now receive treatment as outpatients [31]. As an inevitable consequence of this transition from inpatient to outpatient care, interactions between patients and the medical staff have decreased, and there is a concern that patient distress is being increasingly under-recognized. In response to this transition in care, we have designed a new program, the 'Distress Screening Program in Ambulatory Care' (DISPAC) program, which can be implemented within the tight schedules of outpatient clinics.

The primary aim of this study was to assess the usefulness of the DISPAC program in real clinical oncology settings. We hypothesized that the use of the DISPAC program would result in the referral of more cancer patients with major depression or adjustment disorders to psycho-oncology services. The secondary aim was to assess the feasibility of the DISPAC program, specifically the implementation of the DIT, the recommendations for referral to psycho-oncology services, and the patients' acceptance of such referrals.

#### Method

#### Study sample

Consecutive patients visiting the outpatient clinic of the 'Breast and Medical Oncology Division' of the National Cancer Center Hospital (NCCH), Japan, during the usual care period when DISPAC was not in use and the intervention period when the DISPAC was in use were eligible. The DISPAC period was designated as a 2-week period in June 2008, and the usual care period was designated as the preceding 2-week period. Patients with a non-cancer diagnosis and who were under 18 years of age were excluded from the study.

We estimated that the rate of referral to psychooncology services for the treatment of major depression and adjustment disorders was 1% during the usual care period and that a 4% improvement could be obtained during the DISPAC period. At a 5% significance level (twosided test) and 80% power, a sample size of 285 patients was needed for each period. As the assignment of clinicians to the outpatient clinic changes according to the day of the week, a study period consisting of a multiple of weeks was needed to avoid a physician bias. Since approximately 250 patients visit the outpatient clinic of the 'Breast and Medical Oncology Division' every week, we concluded that a 2-week study period would be adequate for comparing the usual care period and the DISPAC period.

As the implementation of a psychological screening program is a desirable clinical practice recommended by guidelines, the patients in this study were unlikely to be harmed by the study protocol. Since all the data assessed in this study were obtained as part of routine clinical assessments, we did not obtain written consent from the patients, in accordance with the guidelines of the Japanese Ministry of Health, Labor and Welfare. We obtained institutional review board approval for this study in advance.

#### Distress and Impact Thermometer

The DIT is a two-item self-administered rating scale. We developed the DIT by adding the Impact Thermometer to the Distress Thermometer [21,27,28]. Each 'distress' and 'impact' question consists of an 11-point Likert scale, with possible scores ranging from 0 to 10 and a high score indicating an unfavorable status.

In our previous study [28], the DIT was validated and the optimal cutoff points for detecting major depression and adjustment disorders were determined to be 4 for the 'distress' score and 3 for the 'impact' score. Patients who scored equal or more than both cutoff points were regarded as positive,

and the sensitivity and specificity of the measure were 0.82 and 0.82, respectively.

#### DISPAC procedure

The DISPAC program consists of three stages. In the first stage, consecutive outpatients were approached by nurses in the waiting room prior to the physician's assessment. After a brief instruction, they were invited to complete the DIT and submit the completed form to their attending physicians. As the nurses' time resources were limited and a lengthy period of time could not be spent delivering an introduction, a booklet explaining cancer and distress, the types of care delivered by psychooncology services, and how to complete the DIT was given to the patient at the same time as the DIT.

In the second stage, the attending physician played a central role. The physician collected the completed DIT results from the patients and evaluated the screening result. If the patient scored equal to or more than the cutoff points, the physician recommended that the patient consult a psycho-oncology service. If the patient accepted the recommendation, the attending physician called the head of the psycho-oncology service and scheduled a consultation. As returning to the hospital on a separate day would create a burden for the patient, every effort was made to schedule the appointment on the same day. Considering the tight outpatient schedule, the timing of the psychooncology service consultation was adjusted so that the patient would not be inconvenienced. For example, if a patient had time between an X-ray examination and treatment in the outpatient chemotherapy center, the spare time was used for the consultation.

In the third stage, the patients were seen by either of the two resident psychiatrists, a psychologist, or a nurse specialist, supervised by a staff psychiatrist, and clinical diagnostic interviews based on the DSM-IV criteria were conducted. At the end of the interview, a staff psychiatrist also saw the patients and confirmed the diagnosis and treatment plan. If the patients were diagnosed as having a psychiatric disorder, the patients were provided with psychotherapy, which was mainly supportive-expressive, and/or pharmacotherapy, depending on the medical needs and the patients' wishes.

## Psycho-oncology service referral during the usual care period

During the usual care period, the attending physician recommended a referral to the psychooncology service if they thought that the patient exhibited manifestations of moderate or severe distress. If the patients accepted the recommendation, they were seen by the psychooncology service.

#### Outcome measures

The usefulness of the DISPAC was evaluated by calculating the proportion of patients referred for major depression and adjustment disorders, which was the proportion of patients newly referred to the psycho-oncology service and treated for a diagnosis of major depression or adjustment disorders amongst all the patients who visited the outpatient clinic. The number of patients referred to the psycho-oncology service during both the usual care period and the DISPAC period were confirmed using the computerized database of the psycho-oncology division [32].

The feasibility of the DISPAC was measured as follows. The implementation of the DIT was evaluated by calculating the proportion of patients that were screened, which was the proportion of patients who completed the DIT amongst all the patients who visited the outpatient clinic. Also, we measured the amount of time required for the nurse to instruct each patient regarding the use of the DIT on 20 random occasions. The feasibility of the physician's recommendations for referral to the psycho-oncology service was evaluated by calculating the proportion of patients who were recommended to accept a referral, which was the proportion of patients for whom a referral to the psycho-oncology service was recommended amongst all the positively screened patients. We also asked all the physicians who participated in this project how much extra consultation time was required to recommend a referral to the psychooncology service. The patients' acceptance of the psycho-oncology service referral was evaluated by calculating the proportion that accepted the referral, which was the proportion of patients who accepted the psycho-oncology service referral amongst all the patients who received recommendations.

#### Analysis

The patient characteristics, including information on age, sex, cancer sites, and physician-rated performance status according to the Eastern Cooperative Oncology Group (during the DISPAC period only) were obtained from the patients' charts and were recorded separately for the usual care period and the DISPAC period. The characteristics of the patients treated during the usual care period and the DISPAC period, including age, sex, and cancer sites, were then compared.

The usefulness of the DISPAC was evaluated by comparing the proportion referred for major depression and adjustment disorders during the usual care period and the DISPAC period.