

## 院内がん登録システムについて

貴院にて院内がん登録システム(コンピュータシステム)を運用・導入されている場合、以下の質問についてお答えください。

### 【導入・運用】

■ 院内がん登録システムを導入・運用している。(該当項目に○をつけて下さい)

はい(導入年月 \_\_\_\_\_)・ いいえ

・「いいえ」の場合: 導入予定(年月 \_\_\_\_\_)・ 導入予定なし

■ 導入目的をお教えてください。(該当項目の( )内に○をつけて下さい。複数回答可)

- ( ) 地域がん登録への対応
- ( ) 臓器がん登録への対応
- ( ) 院内がん患者の受療状況の把握
- ( ) 院内がん患者の生存率の計測
- ( ) 病院の対がん医療活動の企画、評価、管理
- ( ) 診療活動の支援
- ( ) 研修、教育活動の支援
- ( ) 研究活動の支援
- ( ) 診療患者の継続受診支援
- ( ) その他 具体的に \_\_\_\_\_

### 【ソフトウェア】

貴院の院内がん登録システムのソフトウェアについてお教えてください。

メーカー名(開発の場合は、開発ベンダー名) \_\_\_\_\_

ソフトウェア名 \_\_\_\_\_

バージョン \_\_\_\_\_

ソフトウェアの形態をお教えてください。(該当項目の( )内に○をつけて下さい。)

( ) スタンドアロン ( ) クライアント・サーバー型 ( ) ウェブ型

### 【データベースソフトウェア】

貴院の院内がん登録システムのソフトウェアに採用されているデータベースソフトウェアについてお教えてください。(該当項目の( )内に○をつけて下さい。)

- Microsoft Access                       Microsoft SQL Server 2000 / 2005  
 Oracle Standard Edition / Enterprise Edition  
 FileMaker Pro  
 PostgreSQL                               MySQL  
 その他 具体的に \_\_\_\_\_

### 【サーバーOS(基本ソフトウェア)】

貴院の院内がん登録システムに採用されているサーバーOS(基本ソフトウェア)についてお教えてください。(該当項目の( )内に○をつけて下さい。)

- Windows NT                               Windows 2000                       Windows XP  
 Windows Server2003                       Linux                                       Sun Solaris  
 その他 具体的に \_\_\_\_\_

### 【サーバーハードウェア】

貴院の院内がん登録システムに採用されているサーバーハードウェアについてお教えてください。

■ コンピュータ・サーバー メーカー名 \_\_\_\_\_ 製品名 \_\_\_\_\_

■ CPU \_\_\_\_\_

■ メモリ容量 \_\_\_\_\_

■ ハードディスク容量 \_\_\_\_\_

### 【システム接続・連携】

貴院の院内がん登録システムと病院情報システムとの接続・連携についてお教えてください  
(本アンケート末尾:病院情報システム調査票)

### 【費用】

貴院の院内がん登録システムの費用についてお教えてください。

システム全体      初期費用: \_\_\_\_\_ 万円      年間費用(初期以外) \_\_\_\_\_ 万円  
(ソフトウェア      初期費用: \_\_\_\_\_ 万円      年間費用(初期以外) \_\_\_\_\_ 万円)  
(ハードウェア      初期費用: \_\_\_\_\_ 万円      年間費用(初期以外) \_\_\_\_\_ 万円)

### 【システム導入・運用・管理】

貴院の院内がん登録システムの導入・運用・管理についてお教えてください。

院内がん登録システムの導入・インストールは、( 自院 ・ システム会社 )が行った。

院内がん登録システムの運用管理部署名 \_\_\_\_\_

管理要員 \_\_\_\_\_ 人月

### 【登録件数】

貴院の院内がん登録システムへの登録件数についてお教えてください。

総登録数(概数) \_\_\_\_\_ 件

月間登録数(概数) \_\_\_\_\_ 件

### 【登録方法・担当】

貴院の院内がん登録システムへの登録方法・担当についてお教えてください。

(表中の該当項目に○をつけてください。)

	医 師	事 務 員 ( 課/室)	がん登録 実務担当者	看 護 師	そ の 他 ( )
腫瘍見つけ出し					
登録(登録票記入)					
登録(入力)					
登録内容検証・確定					

### 【登録タイミング】

貴院の院内がん登録システムに腫瘍データの登録を実施するタイミングをお教えてください。

(該当項目の( )内に○をつけてください。)

( ) 診断時に実施 ( ) 退院時に実施 ( ) データ提出時にまとめて実施

( ) その他 具体的に \_\_\_\_\_

**【登録項目】**

貴院の院内がん登録システムで登録を行っている項目についてお教えてください。(該当項目の  
( )内に○をつけて下さい。複数回答可)

- ( ) 院内がん登録標準項目
- ( ) 臓器がん登録(各学会事業)
  
- ( ) 患者基本情報
- ( ) 入退院情報
- ( ) 病名情報
- ( ) 手術情報
- ( ) 医療費情報
- ( ) その他 (具体的に \_\_\_\_\_)

## 【機能】

貴院の院内がん登録システムで使用している機能と満足度についてお教えてください。

(該当項目の( )内に、1～5の数値

- 5: 非常に満足
- 4: 満足
- 3: 普通
- 2: 不満
- 1: 非常に不満

を記入してください。複数回答可)

業務	機能
症例見つけ出し	( )連携システムからの自動抽出 ( )外部ファイルインポート
登録業務	( )患者基本情報、( )診断情報登録、( )腫瘍情報登録、 ( )初回治癒情報、 ( )予後情報登録、( )施設情報登録、 ( )院内がん登録標準項目、 ( )臓器がん登録項目(各学会調査項目)
品質管理	( )単項目チェック、( )項目間チェック、( )複合チェック、 ( )コードチェック、( )範囲チェック、( )列挙チェック、 ( )形式チェック、( )必須チェック
予後調査	( )住所による症例抽出
登録票等出力	( )地域がん登録個票出力、 ( )地域がん登録施設票出力、 ( )紹介状出力
データ・ファイル入出力	ファイル入力: ( )CSV、( )エクセル、( )XML ファイル出力: ( )CSV、( )エクセル、( )XML
検索	( )患者疾病情報一覧、( )個票出力一覧、( )全文検索
システム導入	( )自動インストール機能(インストーラー)、( )データ移行
システム管理	( )登録票作成・管理、( )ユーザー管理、( )マスター管理、 ( )バックアップ、( )画面デザイン設定
セキュリティ	( )ユーザー認証、( )データベース暗号化、 ( )出力データ・ファイル暗号化
マニュアル	( )導入・インストールマニュアル、( )管理・運用マニュアル、 ( )ユーザーマニュアル

院内がん登録システムで、前表に挙げた機能以外に必要なと思われる機能をお教えてください。

必要機能: \_\_\_\_\_

### 【データ集計・解析機能】

貴院の院内がん登録システムで使用している集計機能と満足度についてお教えてください。

(該当項目の( )内に、1～5の数値

- 5: 非常に満足
- 4: 満足
- 3: 普通
- 2: 不満
- 1: 非常に不満

を記入してください。複数回答可)

- ( ) 診療科別集計
- ( ) 期間別集計(在院期間、月、年)
- ( ) 診断名・コード別集計
- ( ) 組織診断名・コード別集計
- ( ) 年齢階層別集計
- ( ) 転帰別集計
- ( ) 病期分類別集計
- ( ) 部位別集計
- ( ) 性別集計
- ( ) 治療内容別集計
- ( ) 診断時居住地域別集計
  
- ( ) 生存率計算

院内がん登録システムで、上表に挙げた集計解析項目以外に必要なと思われる項目をお教えてください。

必要項目: \_\_\_\_\_



## 【効果】

貴院の院内がん登録システムの運用により実現できたことをお教えてください。

(該当項目の( )内に、1～5の数値

5: 完全に実現できた

4: ほぼ実現できた

3: ある程度実現できた

2: 少し実現できた

1: 全く実現できていない

を記入してください。複数回答可)

( ) 地域がん登録への対応

( ) 臓器がん登録への対応

( ) 院内がん患者の受療状況の把握

( ) 院内がん患者の生存率の計測

( ) 病院の対がん医療活動の企画、評価、管理

( ) 診療活動の支援

( ) 研修、教育活動の支援

( ) 研究活動の支援

( ) 診療患者の継続受診支援

( ) その他 具体的に

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## 症例登録システムについて

症例登録システムについてお教えてください。

(症例登録システムとは、がん登録に限らず、あらゆる傷病について登録・検索・出力できるものを指します)

### 【目的】

貴院にて症例登録システムの導入を検討する際に導入目的となる項目をお教えてください。(該当項目の( )内に○をつけてください。複数回答可)

- ( ) 各学会の症例調査事業(例:外傷、急性疾患、慢性疾患、手術症例)への対応
  - ( ) 院内がん登録への対応
  - ( ) 地域がん登録への対応
  - ( ) 臓器がん登録への対応
  - ( ) 病院の対がん医療活動の企画、評価、管理
  - ( ) 診療活動の支援
  - ( ) 研修、教育活動の支援
  - ( ) 研究活動の支援
  - ( ) 院内での臨床試験(治験)
  - ( ) 多施設臨床試験での症例登録・報告出力
  - ( ) 認定医・専門医申請時の臨床実績報告
  - ( ) 診療患者の追跡調査
  - ( ) その他 具体的に
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### 【システム導入時の検討項目の重要度】

症例登録システムの導入の可否を判断する際に、重要な事項をお教えてください。

(該当項目の( )内に、1～5の数値

- 5: 非常に重要
- 4: かなり重要
- 3: ある程度重要
- 2: 少し重要
- 1: 全く重要ではない

を記入してください。複数回答可)

- ( ) 病院情報システムとの接続・連携
- ( ) 導入・維持費用
- ( ) ソフトウェアのインストールサービス(有償)
- ( ) 導入後のシステムサポートサービス(有償)
- ( ) セキュリティ
- ( ) 汎用性(複数の種類の症例登録事業に対応できる)
- ( ) オープンソースソフトウェア製品  
(オープンソースとは、ソフトウェアの設計図が公開されているもの)

# 病院情報システム調査票

貴院の病院情報システムの導入状況についてお教えてください。

システム導入年月 \_\_\_\_\_

システム導入費用 \_\_\_\_\_ 万円

システム維持費用(年間) \_\_\_\_\_ 万円

貴院の病院情報システムについて下表をご記入ください。

病院情報システム 導入の有無	腫瘍見つけ出しに 活用しているシス テム(Oをつけてく ださい:複数回答 可)	がん登録システムとの 接続・連携の有無	接続・連携項目 (具体的に)	がん登録システムと の接続・連携を望む システム(Oをつけ てください:複数回 答可)	希望する接続・連携 項目
医事会計	(有・無・導入予定)	(有・無)			
処方	(有・無・導入予定)	(有・無)			
注射	(有・無・導入予定)	(有・無)			
検体検査	(有・無・導入予定)	(有・無)			
細菌検査	(有・無・導入予定)	(有・無)			
生理検査	(有・無・導入予定)	(有・無)			
放射線・超音波検査	(有・無・導入予定)	(有・無)			
内視鏡	(有・無・導入予定)	(有・無)			
食事	(有・無・導入予定)	(有・無)			
処置	(有・無・導入予定)	(有・無)			
手術	(有・無・導入予定)	(有・無)			
輸血	(有・無・導入予定)	(有・無)			
病理	(有・無・導入予定)	(有・無)			
病名登録	(有・無・導入予定)	(有・無)			
再診予約	(有・無・導入予定)	(有・無)			
入退院移動	(有・無・導入予定)	(有・無)			
電子カルテ(診療録)	(有・無・導入予定)	(有・無)			
看護支援システム	(有・無・導入予定)	(有・無)			
その他( )	(有・無・導入予定)	(有・無)			

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## Detailed Analysis of Visitors to Cancer-Related Web Sites

**TO THE EDITOR:** Web sites are a valuable source of information for cancer patients.<sup>1</sup> Patients are seeking information necessary for their own treatment, as well as general cancer information. To satisfy such needs of cancer patients, it is necessary to build Web sites that are conducive to patients' individual needs, as well as to have organic linkage between a wide variety of sites. Although achieving this end requires sufficient study of the characteristics of cancer-related Web site users, there is little research on the topic, leaving an unclear picture of the actual state of cancer-related Web site users. Therefore, in this study, we conducted an access analysis

of cancer-related Web sites to shed light on the characteristics of their visitors, which is information necessary for improving the user friendliness of such Web sites.

Using Keyword Advice Tool (Overture KK, Tokyo, Japan),<sup>2</sup> we first selected 96 keywords pertaining to cancer that have been used in more than 3,000 searches per month on Yahoo! as of September 2006. Next, we used the 96 selected keywords to conduct Yahoo! searches,<sup>3</sup> and then selected 2,000 Web sites that came up in these searches. We then used Keyword Advice Tool to obtain the number of searches performed with each keyword and ranked the Web sites proportionate to the number of searches. Then we computed a ranking score by giving the *n*th-ranking keyword of the converted ranking a  $1/n$  value (eg, the first-ranking site gets 1,000 points, the second-ranking site half of that, and so on). We

**Table 1.** Web Sites Analyzed

Classification	Name of Web Site	Aggregation Period	No. of Visitors (daily average)	No. of Page Views (daily average)
Cancer center	Cancer center Web site A	September 1, 2006 to November 30, 2006	—	42,663
Cancer center	Cancer center Web site B	October 1, 2006 to November 30, 2006	—	62,181
Hospital	Hospital Web site C	August 1, 2006 to November 30, 2006	8026	—
Hospital	Cancer center Web site D	March 26, 2006 to November 18, 2006; October 15, 2006 to January 13, 2007	—	—
Hospital	Hospital Web site D	October 1, 2006 to December 31, 2006	—	421
Hospital	Hospital Web site E	November 1, 2006 to December 31, 2006	—	—
Pharmaceutical company	Pharmaceutical company Web site A	November 1, 2006 to December 31, 2006	—	—
Pharmaceutical company	Pharmaceutical company Web site B	November 1, 2006 to December 31, 2006	—	—
Pharmaceutical company	Pharmaceutical company Web site C	November 1, 2006 to December 31, 2006	—	—
Pharmaceutical company	Pharmaceutical company Web site D	November 1, 2006 to December 31, 2006	—	—
Pharmaceutical company	Pharmaceutical company Web site E	November 1, 2006 to December 31, 2006	—	—
Individual	Individual antiaging Web site A	December 1, 2006 to December 31, 2006	—	—
Cancer patient	Cancer blog B	October 1, 2006 to December 31, 2006	—	—
Cancer patient	Cancer blog C	October 1, 2006 to December 31, 2006	—	—
Cancer patient	Cancer blog D	December 2, 2006 to January 12, 2007	—	—
Cancer patient	Pediatric cancer blog E	December 10, 2006 to January 27, 2007	—	—
Cancer patient	Pediatric cancer blog F	December 10, 2006 to January 27, 2007	—	—
Cancer patient	Childhood leukemia blog G	December 10, 2006 to January 27, 2007	—	—
Cancer patient	Leukemia blog H	October 8, 2006 to January 8, 2007	—	—
Cancer patient	Leukemia blog I	October 6, 2006 to January 5, 2007	—	—
Cancer patient	Breast cancer blog J	January 1, 2007 to February 28, 2007	198	—
Cancer patient	Breast cancer blog K	January 1, 2007 to February 28, 2007	161	—
Cancer patient	Leukemia blog L	January 1, 2007 to February 28, 2007	173	—
Cancer patient	Ureteral cancer blog M	January 1, 2007 to February 28, 2007	51	—
Cancer patient	Individual cancer link site N	January 1, 2007 to February 28, 2007	—	—



also assigned a hit frequency score for the frequency with which each Web site appeared in searches with each of the 96 keywords. We then computed the final score with the product of the ranking score and the hit frequency score and extracted the 100 highest scoring sites as the subject of this study. Blogs in the present study also included homepages on patients' personal experiences fighting cancer.

There are two main methods for conducting access analysis; these are analyzing the Web server logs and obtaining access logs through JavaScript tags embedded in each page of a Web site.<sup>4</sup> Both methods require the site author to collect the log data. It is possible to obtain the Uniform Resource Locator (URL) of the pages visited, the page viewed before visiting the site, the Internet Protocol (IP) address of the visitors, and the time of visit. In this study, we requested the following information from the selected 100 Web sites. We requested a summary of aggregated results from the Web sites already compiling access data on their own. For the Web sites that are not compiling access data on their own but that can obtain a server log, we obtained the access logs from the site authors and then compiled the data ourselves. For all of the other Web sites, we embedded tags to collect data for the purposes of this study and compiled the data.

Of the sites, 25 Web sites complied with our request and consented to participate in the study; characteristics of these sites are listed in Table 1. Each site operator agreed to participate in the study on the condition of anonymity. The number of visitors to cancer center sites was overwhelmingly higher than the number of visitors to cancer patients' blogs.

We were able to obtain data on page views by day of the week for three Web sites operated by cancer centers and general hospitals (Fig 1). Page views on nonworking days for all three sites were 64% to 70% of page views on weekdays.

We were able to analyze the number of visitors to one hospital Web site (hospital Web site C) and four cancer patients' blogs every 3 hours. The number of visitors to hospital Web site C peaked on weekdays around 12:00 to 3:00 PM. However, there were no evident day-to-day fluctuations on cancer patients' sites, whose accesses peaked around 9:00 PM to 12:00 AM. Although the average number of visitors per hour to hospital Web site C outside of business hours decreased to 38% of the number during business hours (from 9:00 AM to 6:00 PM on weekdays), the average number of visitors to the four cancer patients' blog sites decreased to only 61% (Fig 2).

The ratio of search engines used to access each Web site is shown in Table 2. The percentage of people who used MSN was lower for visitors to cancer patients' blogs than for visitors of hospital sites.

We were able to attain the repeat rate for six cancer patients' blog sites. Although the repeat rates for leukemia and ureteral cancer patients' blogs were extremely low, the repeat rate for breast cancer-related blog sites was high (Table 2). We compared four cancer patients' blog sites for which we were able to obtain this data (Fig 3). There was a group of visitors with a high degree of familiarity for each of the two breast cancer patients' blog sites. There was a smaller group of visitors familiar for leukemia blog L compared with the two breast cancer patients' blog sites. We found a group of visitors tending towards defection for ureteral cancer blog M.

We were able to obtain data on changes in visit frequency over the last year or more for cancer center Web site A, pharmaceutical company Web site A, pharmaceutical company Web site B, and pharma-

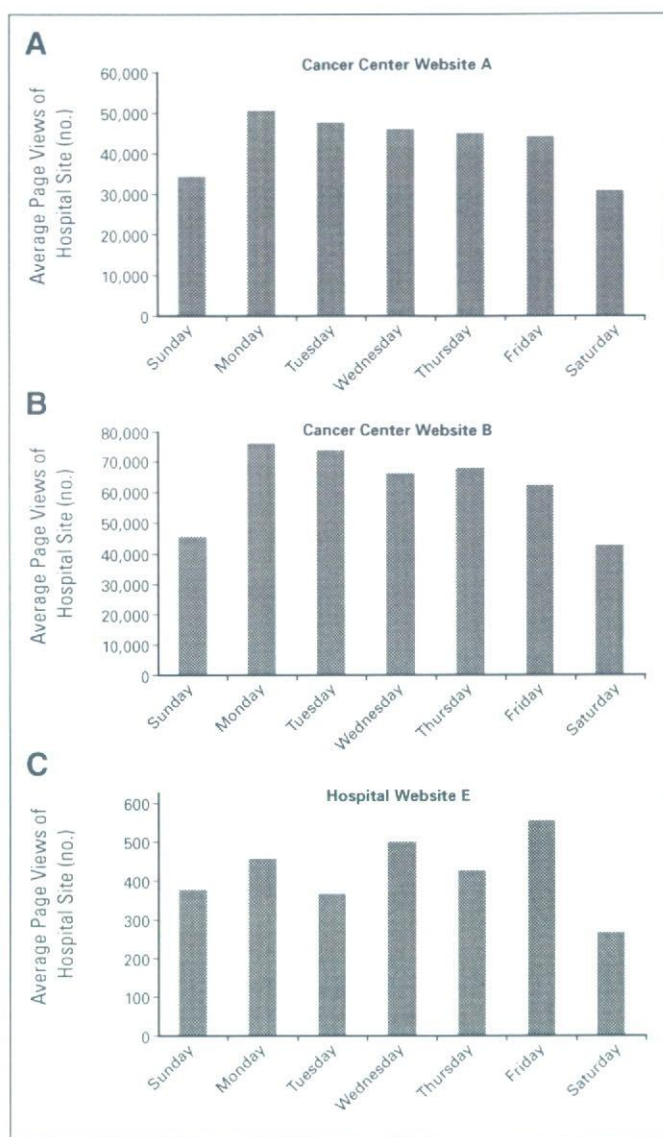


Fig 1. Average page views of hospital site by day of the week.

ceutical company Web site E. Although visit frequency for each site exhibited small fluctuations and overall increasing and decreasing trends, we did not observe any so-called seasonal variations. Furthermore, when we examined 3-month logs of search keywords that led to cancer blog C, we found no visible changes in search keywords during the 3-month period.

We selected Web sites in a wide range of categories for this study. In addition to hospital and pharmaceutical company Web sites, we also targeted a large number of homepage sites on patients' personal experiences fighting cancer. We first screened for sites that are influential among users. Cancer patients' homepage sites constituted 9% of the influential sites initially selected. Previous studies, however, have not focused on these cancer patients' homepage sites.<sup>1,5-8</sup> Blogging on one's experiences with cancer has enabled the flow of information among patients that goes beyond time and space. Homepages provide a means for communication among patients and their families that is more convenient and costs less than traditional face-to-face patient organizations. It is possible that these sites provide information that is



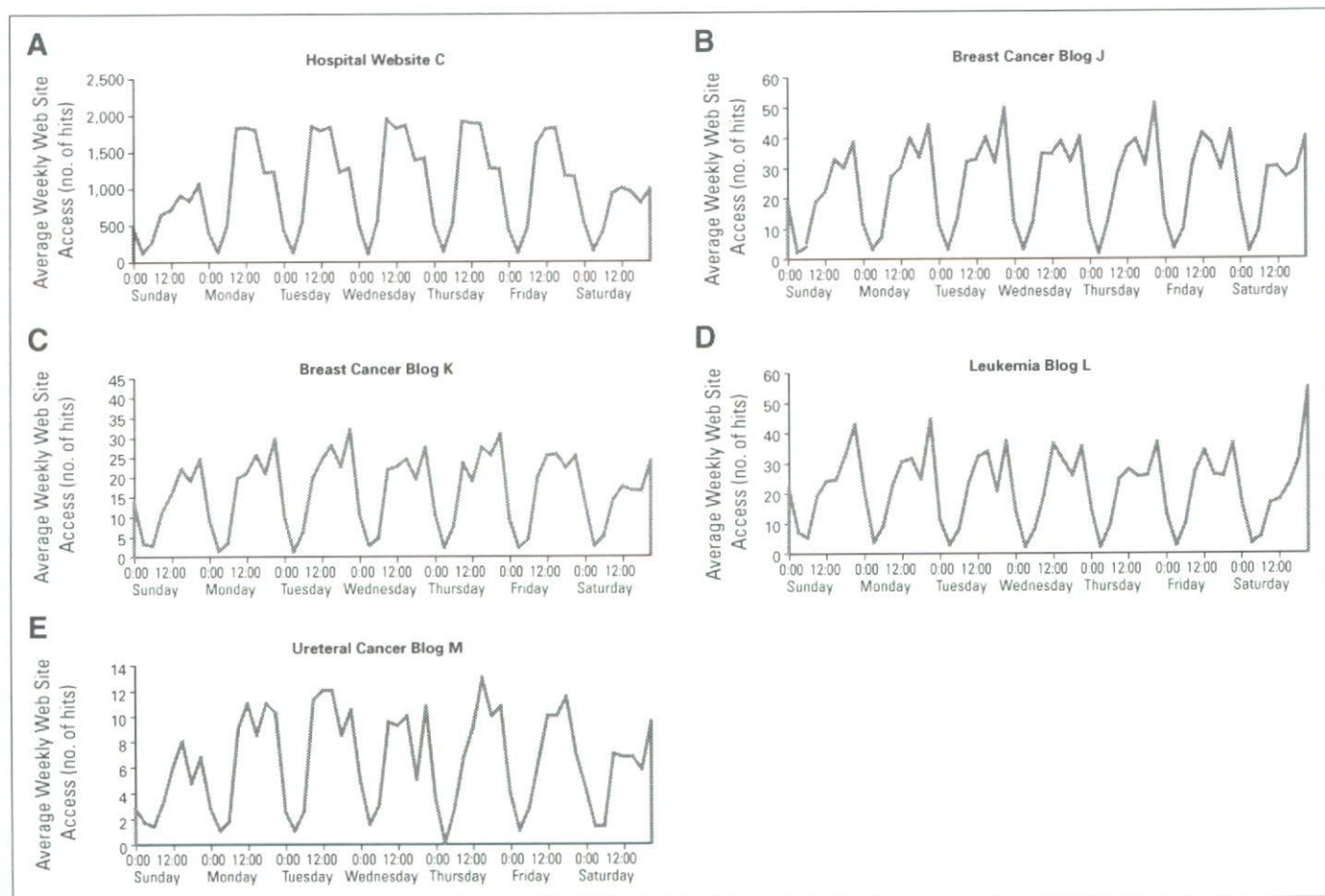


Fig 2. Average weekly access to homepages on fighting cancer. The value on the y-axis is number of accesses to the site every 3 hours.

not provided by medical care providers but that is useful to patients. It is likely that patients' blog sites will become an important category of Web sites in the future.

This study showed that visitors' access patterns vary among different types of Web sites. Many people visited hospital-type sites on weekday afternoons, whereas few visited these sites on non-working days. In contrast, there was hardly any variation between days of the week in visits to cancer patients' blogs, which peaked at night (Fig 1). This fact demonstrates that the background or the status of use varies between users of hospital-type sites and homepage sites. Although we cannot draw any definitive conclusions as a result of insufficiently detailed data, we can infer from the fact that the peak in visits to hospital-type sites coincided with hospital consultation hours that many of these people use these sites as they prepare for hospital visits. At the same time, we can also deduce that there is a tendency for people to visit cancer patients' blogs during their spare time. This may reflect the fact that people use cancer patients' blogs not for one-way transmission of information but as a tool for communication among patients and their family members.

In this study, the rate of visitors who use MSN<sup>9</sup> to reach cancer-related Web sites was generally low compared with the Japanese national average. Moreover, cancer patients' homepage visitors tended to go through Yahoo! and Google<sup>10</sup> more often than MSN compared

with visitors to other categories of Web sites. In general, people who frequently access the Internet use Google, whereas those who access it less frequently use Yahoo!, and those who access the Internet even less frequently use MSN, which comes bundled in many computers' initial setup configuration. Considering this, we can deduce that visitors to cancer-related Web sites and, in particular, to cancer patients' homepages are highly literate with information technology and frequently access the Internet.

This study demonstrated that the repeat rate of visitors varies depending on the attributes of particular Web sites. The repeat rate of visitors to breast cancer-related homepages was extremely high compared with the average repeat rate of information service-type sites, which is approximately 25% to 30% (T. Nobue, personal communication, 2006). We observed the same trend from the results of visitor familiarity as well. This indicates that there are many avid fans of breast cancer-related homepages, which represents a significant departure from information service-type sites such as those of cancer centers. Even among cancer-related homepages, the repeat rate for leukemia-related sites was extremely low. There are a number of possible reasons for this. First, compared with breast cancer, there are many different subtypes of leukemia, with varying symptoms and duration. Therefore, visitors may more often find that the leukemia-related Web site they visited was not describing the exact subtype of leukemia they intended to look up. Second, the

**Table 2.** Characteristics of Sites for Which Data Were Obtainable

Name of Site	Search Engine Ratio ( $\sqrt{\text{Google.co.jp}^* + \text{Google.com}^\dagger}$ )		Repeat Ratio (%)
	Yahoo‡	MSN§	
Cancer center Web site A	1.67	0.16	—
Cancer center Web site B	1.05	0.14	—
Cancer center Web site D	2.17	0.20	—
Hospital Web site E	7.13	0.89	—
Hospital Web site F	2.25	0.02	—
Pharmaceutical company Web site A	1.84	0.14	—
Pharmaceutical company Web site B	4.92	0.18	—
Pharmaceutical company Web site C	6.00	0.40	—
Pharmaceutical company Web site D	4.00	0.29	—
Cancer blog B	6.39	0.16	—
Pediatric cancer blog E	—	—	55.30
Leukemia blog I	1.50	0.08	—
Breast cancer blog J	2.87	0.08	44.60
Breast cancer blog K	1.66	0.08	29.30
Leukemia blog L	0.90	0.30	5.60
Ureteral cancer blog M	1.80	0.05	13.80
Individual cancer link site N	0.72	0.09	9.30
Throughout Japan	1.86	0.51	—
Kameda Medical Center	0.35	0.10	—
Hula dance class for homemakers	8.14	0.63	—
Optical device company	0.92	0.15	—

\*Web site: <http://www.google.co.jp/>.†Web site: <http://www.google.com/>.‡Web site: <http://www.yahoo.co.jp/>.§Web site: <http://jp.msn.com/>.||Web site: <http://internet.watch.impress.co.jp/cda/event/2006/04/21/11756.html>.

¶Shows the percentage when OCN is set to 1.

more visitors at the Web sites related to the types of cancer that occur at an earlier age, such as breast cancer.

To our knowledge, this study was the first to shed light on the characteristics of cancer-related Web site visits. However, there are a number of issues that need to be considered. First, because the number of sites from which we obtained data is limited, we cannot generalize for all cancer-related Web sites. More large-scale studies with a wider scope of target sites will be needed in the future. Second, this study demonstrated that homepage sites on people's personal experiences fighting disease are forums for the communication of information among patients. It is possible for patients and their families to obtain information through these sites that they cannot get from medical care providers. With few previous studies on these sites, more research is needed on the role of these sites in improving patient literacy, as well as the limitations of these homepage sites. Finally, this study showed that the background and behavior of cancer Web site visitors differ among different types of Web sites. This suggests that visitors have diverse needs. Cancer-related Web sites need to be designed from this perspective to make them easy to use and beneficial to their users.

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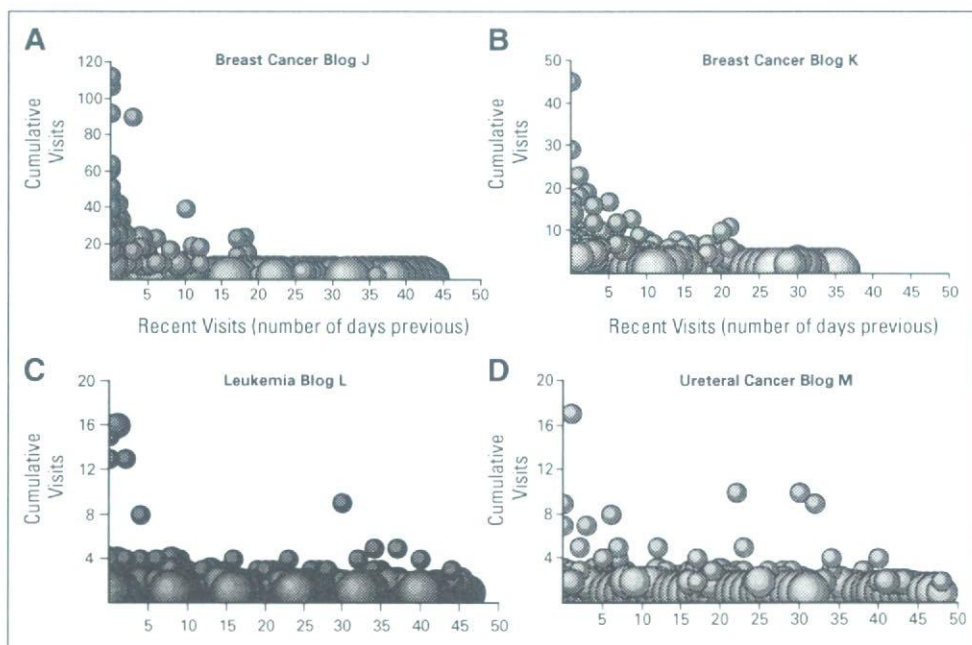
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survival rate is higher and the duration of illness is longer for breast cancer than for leukemia. Third, because information technology is less diffuse among elderly individuals, it is possible that there are



**Fig 3.** Distribution of visitor familiarity and defection. The size of the spheres indicates the amount of aggregated data.



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**AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**

The author(s) indicated no potential conflicts of interest.

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## Cetuximab Pharmacokinetics in End-Stage Kidney Disease Under Hemodialysis

**TO THE EDITOR:** Cetuximab, an anti-epidermal growth factor receptor chimeric mouse/human immunoglobulin 1 monoclonal antibody against the epidermal growth factor (Merck, Darmstadt, Germany), has been approved as a treatment for advanced head and neck cancer in combination with radiation therapy.<sup>1,2</sup> However, there is very little data on cetuximab in patients undergoing chronic dialysis.<sup>3</sup> The treatment of cancer in patients with impaired renal function is an emerging problem because the population is getting older and the rate of chronic dialysis increases by 5% yearly in Western countries. We report a pharmacokinetic study of cetuximab in a patient with renal insufficiency requiring hemodialysis. Cetuximab was instituted at a dose of 250 mg/kg weekly for a 55-year-old patient with head and neck cancer.

We characterized the pharmacokinetics and efficacy of cetuximab at conventional efficacious dose levels in combination with radiation therapy in a hemodialyzed patient with head and neck cancer. The aim of the study was to determine whether conventional doses of cetuximab in combination with radiotherapy were appropriate for hemodialyzed patients.

Cetuximab serum concentration was measured by a validated enzyme-linked immunosorbent assay. The enzyme-linked immunosorbent assay method used a recombinant human epidermal growth factor receptor (extracellular domain) adsorbed onto microtiter plates to capture cetuximab in serum. The captured cetuximab was detected using a peroxidase-conjugated goat antihuman F(ab')<sub>2</sub> specific for Fc

fragment (horseradish peroxidase anti-human immunoglobulin G). Lower limit of quantitation and upper limit of quantitation were 0.75 and 15 µg/mL, respectively. The limit of detection was 0.012 µg/mL. Concentrations higher than the upper limit of quantification were diluted 1:10 or 1:100, deviation and variability of this procedure being lower than 4.5%. Serum samples were used to estimate cetuximab pharmacokinetics, assuming no time-dependence, with WINNonlin (Scientific Consultant, Apex, NC; Pharsight Corporation). One- and two-compartment models with first order distribution and elimination constants were tested. The best model was selected using the usual methods, which included the analysis of plots of observed versus predicted concentrations and the Akaike information criteria. The model that best fitted the observed data was a two-compartment model with first-order elimination from the central compartment (Fig 1). Clearance from central compartment was 0.025 L/h, central compartment volume was 3.8 L, and terminal elimination half-life was 11.9 days (Table 1).

Although analyses of cetuximab pharmacokinetics were previously reported, the results obtained in our patient cannot be readily compared with these publications. Tan et al<sup>4</sup> did not use a formal compartment model. In the studies of Baselga et al<sup>5</sup> and Delbaldo et al,<sup>6</sup> cetuximab pharmacokinetics were described by a one-compartment model. However, a two-compartment model has previously been shown to be the best to describe the pharmacokinetics of immunoglobulin 1 monoclonal antibodies, including trastuzumab,<sup>7</sup> inolimomab,<sup>8</sup> rituximab,<sup>9</sup> basiliximab,<sup>10</sup> clenoliximab,<sup>11</sup> alemtuzumab,<sup>12</sup> and adalimumab.<sup>13</sup> Dirks et al<sup>14</sup> used a two-compartment model but with a Michaelis-Menten type of elimination. This last approach necessitates a large number of patients and the study of different dose regimens, and could not be applied to our patient.



## Favourable long-term results after surgical removal of lung metastases of breast cancer

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**Abstract** We retrospectively evaluated whether a surgical strategy benefits patients with operable lung metastasis of breast cancer. Between 1960 and 2000, 90 patients (mean age 55.1; range 32–77) with lung metastasis (79 solitary, 11 multiple) underwent surgery as follows: wedge resection ( $n = 10$ ), segmental resection ( $n = 11$ ), lobectomy ( $n = 68$ ) and pneumonectomy ( $n = 1$ ). The metastases were completely resected in 89% of them. One patient died due to surgical complications. The overall 5- and 10-year cumulative overall survival rates were 54% and 40%, respectively (median, 6.3 years). Fifteen patients survived without relapse for over 10 years. They were 24% of those who progressed for 10 years or more after lung surgery. The most significant prognostic factor was disease-free interval (DFI) and stage at breast surgery. The 10-year survival rates of those with  $\geq 3$  and  $< 3$  years of DFI were 47% and 26%, respectively ( $P = 0.014$ ). Survival times were significantly longer for patients with clinical stage I at breast surgery than those with stage II–IV ( $P = 0.013$ ). Our data, although limited and highly selective, suggest that surgical approach to lung metastasis from breast cancer may prolong survival in certain subgroups of patients to a greater extent than systemic chemotherapy alone. Surgical approach to lung

metastasis of breast cancer, if possible, should be a treatment of choice to a great extent.

**Keywords** Breast cancer · Lung metastasis · Pulmonary metastasis · Surgery · Prognosis · Cure rate · Long survival

### Introduction

Recent advancements in adjuvant chemotherapy and hormone therapy have significantly reduced the recurrence rate and increased the overall survival times of patients with operable breast cancer [1, 2]. However, once patients relapse, cure rates after systemic treatments remain hopelessly low [3, 4]. Thus, metastatic breast cancer is thought to be incurable [5] and systemic treatments are used for palliative under such circumstances [6, 7].

The lung is one of the most common sites of recurrent metastasis from breast cancer. Surgery has seldom been the treatment of choice since it is considered a manifestation of a systemic disease. Several studies of surgical approaches have indicated promising results [8–12], but most medical oncologists disapprove of surgical strategies.

Considering the poor results of systemic treatments, we postulated that surgical resection of operable lung metastases with postoperative systemic treatments might prolong survival times more than systemic treatments alone. Here, we describe a surgical approach to treating lung metastasis from breast cancer and discuss the controversial nature of this strategy.

### Patients and methods

Our principal indications for surgical intervention to treat lung metastasis consisted of a solitary and operable lung

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metastasis, no clinical evidence of other recurrent lesions, no serious complications, written informed consent to undergo surgery after understanding the associated risks and remaining alive for at least 6 months.

Chest X-rays were taken every 6 months after treating the primary breast cancer to detect recurrence. Suspected lung metastasis was confirmed by CT scanning and bronchoscopy, which also evaluated the feasibility of surgery. Cytological assessment of specimens obtained by trans-bronchoscopic aspiration cytology (TBAC), trans-bronchial lung biopsy (TBLB) or CT-guided trans-cutaneous aspiration cytology was performed for almost all patients. Recurrent lesions outside the lung were investigated using X-rays, bone scintigraphy, ultrasonography, CT scanning and more recently FDG-PET scanning to avoid selecting inappropriate candidates for surgery. After confirming lung metastasis, patients were followed up from 2 until 388 weeks (mean, 14.8 weeks) to reconfirm the diagnosis and to determine surgical indications. Some patients who had undergone systemic front-line therapy but whose metastasis failed to respond were also candidates for surgical treatment. Lung and cardiac functions and other general conditions were also assessed to minimize surgical risk.

Between June 1960 and October 2000, 90 women with breast cancer underwent surgery to treat lung metastases. Among them, four had been treated for loco-regional skin and/or regional lymph node metastases surgically or radiologically and had been under complete remission before lung metastases, one had stage IV breast cancer with lung metastasis, and 85 had lung metastases as the first site of recurrence. Among these patients, 70 underwent breast surgery at our hospital and the remaining 20 were referred to our institution from other hospitals.

During the same period, 382 patients developed lung metastases as the first site of recurrence among 13,477 women with primary breast cancer who underwent breast surgery at our hospital. Among the 382 patients, 70 (18%) underwent lung surgery and 312 (82%) underwent systemic treatment alone. Although lung surgery was indicated, the selection of patients was inconsistent and mainly depended on the opinions of the physician in charge.

Clinical status, treatment methods and patient outcomes are listed in Table 1. The mean age of the patients was 55.1 years (range 32–77 years) at surgery for lung metastasis. The mean interval between surgery for the primary breast cancer and the discovery of recurrent disease (disease free interval: DFI) was 5.6 years (range 0–20.4 years).

Preoperative estimation of the largest metastatic lung tumour varied from 0.8 to 4.8 cm (mean, 2.3 cm). Preoperative estimations of the numbers of lung metastases were solitary in 79 patients, two in 9 patients, and three or more in 2 patients. None of the patients had bilateral lung metastasis, except one who had undergone lobectomy

**Table 1** Patient characteristics

Characteristics	Number	%
Age (years)		
≤40	6	7
41–50	26	29
51–60	30	33
≥61	28	31
Mean (range)	55.1 (32–77)	
Disease-free interval (years)		
<3	33	37
≥3	57	63
Mean (range)	5.6 (0–20.4)	
Size of largest metastasis (cm)		
≤2	44	49
>2	46	51
Mean (range)	2.2(0.8–4.8)	
Numbers of lung metastases, preoperatively		
One	78	88
Two	7	10
Three or more	5	2
Method of surgery		
Wedge resection	10	11
Segmental resection	11	12
Lobectomy	68	76
Pneumonectomy	1	1
Nodal dissection		
Done	84	93
Not done	6	7

twice to treat bilateral lung metastasis, the second being 4 years after the first.

The lung, pleural cavity and mediastinal node status was also intra-operatively assessed by the surgeon to reach a final decision about surgical resection of lung metastasis. In fact, the number of metastatic lesions in the lung in six patients was higher than that diagnosed preoperatively, and pleural dissemination was evident in 4 patients. Basically, hilar and unilateral mediastinal lymph nodes were simultaneously dissected. The postoperative systemic treatment was not uniform, but consisted essentially of standard systemic regimens at that time.

Survival was estimated by the Kaplan–Meier product-limit method from the date of surgical removal of lung metastasis to the date of death or of the last observation. Possible prognostic factors after surgery included DFI, clinical manifestations of nodal involvements at the hilus of the lung and/or the mediastinum, preoperative estimations of the number and the size of the largest lung metastasis, stage at breast surgery and others. The log-rank test (or Wilcoxon test) evaluated the significance of differences between survival curves.



## Results

The operative procedures consisted of wedge resection ( $n = 10$  patients), segmental resection ( $n = 11$ ), lobectomy ( $n = 68$ ) and pneumonectomy ( $n = 1$ ) were selected. Eighty and 10 patients underwent curative and palliative procedures, respectively. The reasons for the palliative operations were pleural dissemination ( $n = 4$ ), incomplete resection of lung metastasis ( $n = 3$ ), and incomplete resections of lymph node metastasis ( $n = 3$ ). After surgery, 78 patients had a single metastasis, seven had two, two had three, and two had four metastases. All 90 patients had histologically proven metastatic lung metastasis from breast cancer.

The lymph nodes were dissected in 81 patients and lymph nodes were sampled from 3. Neither lymph node sampling nor dissection was performed in the remaining 6 patients. Lymph node metastasis was present in 37 patients (44% of dissected or sampled patients), but not in 47. No information regarding nodal involvement was obtained from the remaining 6 patients. Among the 37 patients in whom lymph node metastasis was identified, metastasis was localized at the hilus of the lung and to the mediastinum in 11 and 26 patients, respectively.

Several minor complications developed such as post-operative infection, atelectasis and hepatitis due to blood transfusions. Serious complication developed in one patient who died within 1 month of surgery.

All patients were followed up until death or up to December 2003 or later with a median follow-up of 6.6 years. At the end of December 2003, 62 patients had relapsed again with recurrent disease, 28 had not relapsed. After lung surgery, first relapses were again found in the lungs, pleura, mediastinal lymph nodes, and others in 20, 5, 4, 33, respectively. Patients again relapsed from 3 weeks to 12.6 years (median 35.6 months) after lung surgery excluding palliative surgery. Two patients relapsed 10 years or more after lung surgery.

At the time of this writing, 56 patients are dead and 34 remain alive. Among the deceased patients, 54 died from recurrent disease, 1 from colon cancer and 1 from cerebrovascular disease. Among the survivors, 26 of 34 remain alive without recurrent disease. Twenty-two patients lived for over 10 years after lung surgery (Table 2). Fifteen of these remained free of recurrence for over 10-years, and 3 remained alive with recurrence, 4 died from recurrent diseases, one from contralateral breast cancer and 1 from colon cancer. Among 63 patients who progressed over 10-years from lung surgery, 15 (24%) survived for 10 years or more without further relapse. The longest survival time without relapse was 24.7 years after lung surgery.

The median overall cumulative survival time was 6.3 years, and the 5-, 10-, 20-year cumulative overall

survival rates after lung surgery were 54, 40, and 25%, respectively (Fig. 1).

Table 3 shows the effects of possible prognostic factors that might affect survival after lung surgery. The most significant factors for survival after lung surgery were DFI and clinical stage at breast surgery. The 10-year overall survival rate for 33 patients with <3 year DFI was 26%, whereas that for 57 patients with  $\geq 3$ -year DFI was 47%. The difference was statistically significant ( $P = 0.014$ , log-rank test). Similarly, the 10-year overall survival rate for 20 patients with clinical stage I at breast surgery was 74%, which was significantly higher than that for patients with stage II–IV ( $P = 0.013$ , log-rank test). The biggest size of metastasis and the presence of nodal metastases of the lung were marginally significant prognostic factors. The prognosis of patients with large tumours of  $\leq 2$  cm was significantly more favourable than that of patients with tumours that were  $>2$  cm ( $P = 0.043$  in Wilcoxon test). The number of metastasis, type of lung surgery, age at lung surgery and others did not affect survival significantly. Lymph node dissection and curability did not also affect survival probably because of the small number.

The 10-year cumulative survival rate of 312 patients with lung metastases as the first site of recurrence and who underwent systemic chemo- and hormonal treatment alone was 6.5% and the median length of survival was 2.2 years. Among them, 11 patients survived for over 10 years, but eventually eight died from recurrent disease and only three remain alive without disease. Indeed, the extent or the status of metastatic diseases differed, but these survival data are obviously worse than those obtained from patients who underwent lung surgery.

## Discussion

Based on the assumption that metastatic breast cancer is a systemic disease, medical oncologists usually do not recommend surgical procedures for metastatic breast cancer or consider them only as palliative strategies [6]. Only systemic treatments are routinely considered for such patients. Yet recent systemic approaches even with anthracycline and/or taxanes have achieved small progress in terms of prolonging life expectancy [5, 6, 12]. High-dose chemotherapy with stem-cell transplantation has also failed to prolong survival times [13]. The median survival after chemotherapy remains at around 24 months, and cure rate is hopelessly low [3]. Thus, metastatic breast cancer is still regarded as incurable, and treatment is usually only palliative [4, 5]. Indeed, this may be true for most patients, but we found that some patients survived for long periods and some of them seemed to be cured of metastatic disease by surgery.

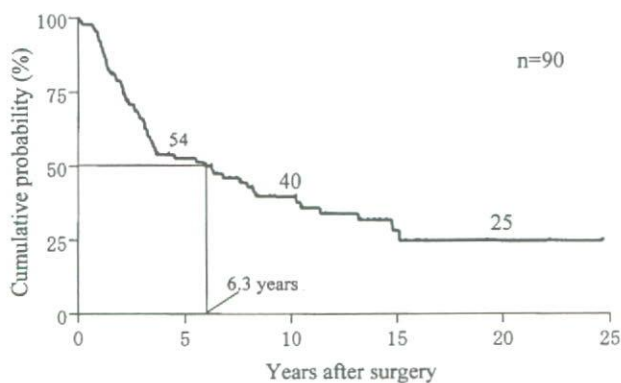
**Table 2** Patients survival over 10 years after surgery for lung metastasis of breast cancer

Patient No.	Age at lung surgery	DFI (years)	Extra-pulmonary metastasis	No. metastasis	Max. metastasis size (cm)	Type of lung surgery	Node metastasis in mediastinum	Chemotherapy after surgery	Survival (years)	Recurrence after surgery	Prognosis
1	45	3.7	No	1	2.8	Lobect.	+	CPA + 5FU	24.7	No	Alive
2	32	1.7	No	1	2.6	Lobect.	-	CMFT	22.2	No	Alive
3	65	6.1	No	1	3.1	Lobect.	-	None	19.3	No	Alive
4	50	1.9	No	1	2.5	Lobect.	-	None	16.4	No	Alive
5	50	8.9	No	1	1.8	Lobect.	-	FACT	16.0	Pleura, brain	Alive with disease
6	57	8.0	No	2	1	Lobect.	-	CMF, FAC	15.9	Lung	Alive with disease
7	74	9.0	No	1	2.5	Lobect.	-	TAM, Ex	15.4	No	Alive
8	62	1.0	No	3	3.2	Lobect.	-	FAC	15.2	No	Alive
9	65	11.5	No	1	3.3	Lobect.	-	FAC	15.1	Liver	Died of BC
10	37	2.3	No	1	1.3	Lobect.	-	None	14.8	No	Died of other BC
11	69	1.2	No	1	1.3	Lobect.	-	FAC, CMF	14.5	No	Alive
12	38	2.4	No	1	3.2	Lobect.	+	FAC	13.9	No	Alive
13	48	5.6	No	1	1.3	Partial	+	FACT	13.6	No	Alive
14	55	4.8	No	1	2	Wedge	Not dissected	CMF	13.3	Lung	Alive with disease
15	58	19.8	No	2	1.2	Lobect.	+	FAC, CMF	13.3	No	Alive
16	55	14.9	Local skin	1	0.7	Lobect.	-	FACT	13.2	Lung	Died of BC
17	49	1.6	No	1	1	Partial	-	CMF	11.9	No	Alive
18	50	7.4	No	1	1.3	Lobect.	-	None	11.4	No	Died of colon cancer
19	50	18.4	No	1	1.9	Lobect.	+	TAM	10.5	No	Alive
20 <sup>a</sup>	59	6.4	No	1	1.5	Lobect.	+	FACT	10.4	Lung <sup>a</sup>	Died of BC
21	50	4.9	No	2	1.7	Lobect.	-	None	10.2	Brain	Died of BC
22	44	10.4	No	1	3.2	Pneumo.	+	None	10.2	No	Alive

*Lobect* lobectomy, *Pneumo* pneumonectomy, *CPA* cyclophosphamide, *5FU* 5-fluorouracil, *CMF* CPA + methotrexate + 5FU, *T* tamoxifen, *FAC* 5FU + doxorubicin + CPA, *BC* breast cancer

<sup>a</sup> Patient underwent second lung surgery

Under these general recognitions, our rationales for surgical treatment of lung metastasis of breast cancer are as follows: (1) To date, survival after lung metastasis has been



**Fig. 1** Cumulative survival curves after surgery for lung metastasis

discouragingly low despite intensive systemic treatment. (2) Several pioneers however, have found that surgical intervention can achieve promising results if curable resection can be performed. (3) Recent advances in lung surgery have rendered surgical resection a much safer operation with minimal physical trauma. (4) Recent advances in imaging techniques, such as CT and FDG-PET scanning, can detect early lung metastasis, allowing the selection of suitable surgical candidates. (5) Experimental tumour models indicate that the results of systemic approaches should be improved when the tumour burden is lowered [14]. (6) In addition to causing lung function to deteriorate, metastatic lung tumours might be a source of other systemic metastases if the tumour burden is large.

Few reports have described the surgical treatment of lung metastasis, but some have indicated promising results (Table 4). Friedel et al. [7] studied 467 patients and



**Table 3** Survival after surgery for lung metastasis according to clinical status

Clinical status	Number of patients	Median (50%) survival (year)	Cumulative 10-year survival rate ( $\pm$ SE)	Significance logrank test (Wilcoxon test)
Overall	90	6.3	39.8 $\pm$ 5.6%	–
Age at lung surgery				
$\leq$ 50 years	32	6.3	46.4 $\pm$ 8.9	NS
>50 years	58	4.5	35.3 $\pm$ 7.2	
Stage at breast surgery				
I	20	>15	74.3 $\pm$ 10.0%	$P = 0.013$
II	53	3.4	29.6 $\pm$ 6.7%	
III/IV	7	3.7	38.1 $\pm$ 19.9%	
Unknown	10	3.1	34.3 $\pm$ 15.9	
Disease-free interval				
<3 years	33	2.4	26.0 $\pm$ 8.1%	$P = 0.014$
$\geq$ 3 years	57	8.2	47.1 $\pm$ 7.3%	
Other recurrence site before lung surgery				
None	85	6.3	41.2 $\pm$ 5.8%	NS
Local recurrence (under control)	5	1.5	20.0 $\pm$ 17.9%	
Number of lung metastasis				
One	78	5.9	39.3 $\pm$ 6.0%	NS
Two or more	12	2.6	41.7 $\pm$ 7.3%	
Biggest size of metastasis				
$\leq$ 2 cm	44	8.2	49.4 $\pm$ 7.9%	$P = 0.168$ ( $P = 0.043$ )
>2 cm	46	3.5	29.7 $\pm$ 7.6%	
Type of surgery				
Wedge or segmental resection	20	6.8	46.5 $\pm$ 13.1%	NS
Lobectomy or pneumonectomy	70	3.5	37.6 $\pm$ 6.1%	
Radicality of surgery				
Curative	80	6.3	41.4 $\pm$ 5.8%	NS
Palliative	10	2.7	–	
Nodal dissection or sampling				
Done	84	5.5	40.2 $\pm$ 5.7%	NS
Not done	6	4.6	26.7 $\pm$ 22.6%	
Nodal metastasis				
Negative (including no information)	53	7.1	44.1 $\pm$ 7.4%	$P = 0.186$
Positive	37	3.2	33.5 $\pm$ 8.4%	

described them in the international registry of lung metastasis. The prognosis of these patients who underwent lung metastatectomy was 38% after 5 years, 22% after 10 years, and 20% after 15 years. Staren et al. [8] reported 5-year survival rates of 36% with a median survival of 55 months in a study of 33 patients. Lanza et al. [9] reported a 5-year survival rate of 50% with a median survival of 47 months in a study of 41 patients. Based on these results, Friedel expressed that lung metastatectomy is currently the best treatment option for selected patients with lung metastasis arising from breast cancer [7]. The present study adds more evidence that the surgical approach to treating lung metastases is beneficial.

The prognostic factors after surgery remain controversial. In the group of completely resected patients, a long DFI was one of the most significant favourable prognostic factors. The DFI was 36 months in this study and in that of Friedel et al. [7], but varies in other studies between 12 and 48 months [9, 15]. Other important factors were the clinical stage of the primary tumour in this study, the number of metastases [16], the biggest size of metastasis in this series [17]. Whether it is true or not, solitary lung metastasis without other remote metastases should be a best candidate, and waiting for several months to ensure a surgical candidate and routine lymph node dissections might have been a factor in our favourable results. Moreover, recent