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ABSTRACT

Purpose
To estimate scenarios for survival for women with metastatic breast cancer (MBC) who are starting chemotherapy.

Patients and Methods
We sought randomized, first-line chemotherapy trials for MBC published from 1999 to 2009. We recorded median progression-free survival (PFS) and median overall survival (OS) and extracted the following percentiles (represented scenario) from each OS curve: 90th (worst-case), 75th (lower-typical), 25th (upper-typical), and 10th (best-case). We also estimated these scenarios for each OS curve by multiplying its median by four simple multiples: 0.25 (worst-case), 0.5 (lower-typical), 2 (upper-typical), and 3 (best-case). Estimates were deemed accurate if they were within 0.75 to 1.33 times the actual value.

Results
From 36 trials (13,083 women), the mean for median PFS was 7.6 months (interquartile range [IQR], 6.0 to 9.0 months), the mean for median OS was 21.7 months (IQR, 18.2 to 24.0 months), and the mean for the ratio of median OS to median PFS was 3.0 (IQR, 2.4 to 3.5). The mean for each OS scenario was worst-case, 6.3 months (IQR, 4.8 to 7.5 months); lower-typical, 11.9 months (IQR, 9.9 to 13.2 months); upper-typical, 36.2 months (IQR, 31.1 to 41.3 months); and best-case, 55.8 months (IQR, 47.5 to 60.2 months). Simple multiples of the median gave accurate estimates of the worst-case scenario in 73% of OS curves, lower-typical in 97%, upper-typical in 95%, and best-case in 96%. OS was longer in trials with higher proportions of estrogen receptor–positive tumors ($P < .001$) and in trials of trastuzumab-treated human epidermal growth factor receptor 2–positive tumors ($P = .001$) and in trials of trastuzumab-treated human epidermal growth factor receptor 2–positive tumors ($P = .001$).

Conclusion
Simple multiples of an OS curve’s median can accurately estimate typical (half to double the median), best-case (triple the median), and worst-case (one quarter of the median) scenarios for survival.

INTRODUCTION

Metastatic breast cancer (MBC) is a heterogeneous disease that is essentially incurable. Most women with MBC receive cytotoxic chemotherapy at some stage of their illness. When starting chemotherapy for MBC, women require an understanding of how their cancer and its treatment will affect their life expectancy. Surveys of patients with advanced cancer suggest that all want information about their future, most want information about their likely survival time, and many want specific estimates of best-case, average, and worst-case scenarios for survival. Information about how to estimate or describe these scenarios is scarce, so it is no surprise that cancer clinicians are often reluctant to estimate and discuss life expectancy.

Survival data from groups of patients with similar characteristics (demographic, disease, and treatment) would be an ideal source of prognostic information but those data are rare. Clinical trials are readily available, easily accessible, and often provide detailed information about survival. Overall survival (OS) curves from clinical trials are usually

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summarized by their median, and although median survival may be
the best single-number description of a survival curve, it is probably
not the best way of explaining prognosis to a patient. Providing pa-
patients with a single-point estimate of survival based on the median
implies unwarranted precision and leaves little room for hope. We
previously proposed that providing estimates for the typical range,
best-case scenarios, and worst-case scenarios for OS might be a better
way of communicating life expectancy and that the percentiles from
an OS curve are a useful basis for estimating these scenarios.5

The purpose of this study was to find and summarize survival
data from recent, randomized trials of first-line chemotherapy for
MBC that would help clinicians estimate and describe prognosis for
their patients in this situation.

PATIENTS AND METHODS

We searched the specialized register maintained by the Secretariat of the
Cochrane Breast Cancer Group (CBCG)6 for references coded as “advanced
breast cancer” and “chemotherapy” published from January 1999 to June 2009
inclusive. The results were supplemented by searches of MEDLINE and the
reference list from a recently published systematic review of MBC-chemother-
apy trials.7

Two authors independently screened the references and selected trials
meeting the following inclusion criteria: randomized trial comparing at least
two different chemotherapy regimens being given as first-line chemotherapy
for women with MBC, including at least 90 patients enrolled per treatment
arm, and Kaplan-Meier curves for OS.

We recorded the year of publication, number of treatment arms, names
and schedules of the chemotherapy agents, number of participants, median
follow-up, patient demographics, and tumor characteristics for each trial. We
recorded the median progression-free survival (PFS) and median OS for each
treatment group.

Each OS curve was independently traced by two authors by using UN-
SCAN-IT graph digitizing software (Silk Scientific, Orem, UT).8 The median
and following percentiles (represented scenarios) were extracted from each OS
curve: 90th (worst-case), 75th (lower-typical), 25th (upper-typical), and 10th
(best-case; Fig 1). One-, 2-, and 5-year survival percentages were also recorded.
Discrepancies were resolved by repeated measurement and discussion.

We expected the shape of each OS curve to be approximately exponential
allowing its percentiles to be estimated by simple multiples of its median. On
the basis of our previous work6,9 and the fact that clinical trial patients are
relatively more homogeneous than an unselected clinical population that
includes a variety of cancers, we hypothesized a priori that the appropriate
simple multiples of the median for each percentile would be 0.25 for the 90th,
0.5 for the 75th, 2 for the 25th, and 3 for the 10th. These values were less
extreme than those for a true exponential distribution in which the 90th
percentile is 0.17 times the median, and the 10th percentile is 3.3 times the
median. We also decided a priori that an estimate would be deemed accurate if
it was within 0.75 to 1.33 times the actual value, our arbitrary range for
reasonable accuracy.

We hypothesized that longer median OS would be observed in trials with the following characteristics: higher proportion of women with estrogen re-
ceptor (ER)–positive tumors, lower proportion of premenopausal women, lower proportion with visceral metastases, higher proportion with Eastern
Cooperative Oncology Group (ECOG) performance status < 2, lower pro-
portion who had received prior adjuvant chemotherapy, use of a taxane, use of
trastuzumab in women with human epidermal growth factor receptor 2 (HER2)–positive tumors, and more recent year of publication. Associations
between these factors and median OS were assessed by using simple linear
regression. The association between median OS and trastuzumab-treated
HER2-positive disease was explored by comparing trials in which all women
were HER2-positive and received trastuzumab with trials in which HER2
status was not checked and no women received trastuzumab. The association
between median OS and use of a taxane was explored by comparing trials in
which all women received a taxane with trials in which no women received a
taxane.

The CBCG register search identified 284 references, and 212 of these
related to randomized chemotherapy trials in MBC. Because many of
these studies were not about first-line therapy, were small, or were
abstracts only with no survival curves, only 27 trials were eligible for
this review. The reasons for exclusion are summarized in Figure 2.
Supplementary searches of MEDLINE and reference lists identified an
additional nine trials. The 36 selected trials included 78 survival curves
and 13,083 patients. Thirty-four studies were published in the peer-
reviewed literature,10-43 and two were published as abstracts only.44,45

A statistically significant difference in PFS was reported in 13 trials
(36%),10-13,17,22,30,31,34,37-39,43 and a significant difference in OS was
reported in seven trials (19%).11,17,23,27,36,38,43

The characteristics of the trials, including the chemotherapy
agents used, are summarized in Table 1. The median follow-up for the
36 trials ranged from 10 months to 102 months with a median of 29
months. Most trials had two treatment groups, and the majority of
women enrolled were postmenopausal with visceral metastases and an
ECOG performance status of 0 or 1. Approximately 50% of women in
these trials had ER-positive tumors. In six trials, trastuzumab was
given with chemotherapy to patients with HER2-positive tumors in at
least one treatment group, and there were two trials in which all
patients enrolled were HER2-positive and all received trastuzumab
with chemotherapy. One trial had not reached median OS in one of its
treatment groups at the time of reporting.45 Similarly, the follow-up
was insufficient for the 25th percentile and 10th percentile to be
obtained from the OS curves in 13 and 27 trials, respectively.

The mean value and interquartile range (IQR) for median PFS
was 7.6 months (IQR, 6.0 to 9.0 months), for median postprogression
survival was 14.0 months (IQR, 10.8 to 15.6 months), for median OS
was 21.7 months (IQR, 18.2 to 24.0 months), and for the ratio of
median OS to median PFS was 3.0 (range, 2.4 to 3.5). The mean value
for 1-year survival was 73% (IQR, 69% to 78%), and the mean value
for 2-year survival was 45% (IQR, 38% to 50%). The mean value for

![Proportion Surviving vs Time Since Study Entry](image-url)
5-year survival was 12% (IQR, 7% to 17%), but this information was available in only 14 trials (39%).

The distribution of the survival times for each of the selected percentiles (scenarios) is shown in Figure 3. Each distribution was roughly symmetrical with a skew to the right (toward longer survival times). Most values for each scenario fell within a relatively narrow range, indicating the remarkable similarity of survival times among these trials. The mean value for each of the scenarios was worst-case, 6.3 months (IQR, 4.8 to 7.5 months); lower-typical, 11.9 months (IQR, 9.9 to 13.2 months); upper-typical, 36.2 months (IQR, 31.1 to

<table>
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<th>References (n = 284)</th>
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<td>Not randomized chemotherapy trials in MBC (n = 87; 23.6%)</td>
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<td>Duplicate references for the same study (n = 22; 7.7%)</td>
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<td>&lt; 90 patients/arm (n = 48; 16.9%)</td>
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<td>No OS curve (n = 19; 6.7%)</td>
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<td>Total included (n = 27; 9.5%)</td>
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**Table 1. Characteristics of the 36 Included Trials**

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Abbreviations: ECOG, Eastern Cooperative Oncology Group; ER, estrogen receptor.

**Fig 2.** Reasons for exclusion of trials. MBC, metastatic breast cancer; OS, overall survival.
41.3 months); and best-case, 55.8 months (IQR, 47.5 to 60.2 months). The median and mean times for each percentile (scenario) were almost identical.

Simple multiples of the median provided accurate estimates of the selected percentiles (scenarios) for most survival curves: $0.25 \times$ median accurately estimated the 90th percentile (worst-case) in 73% of curves, $0.5 \times$ median accurately estimated the 75th percentile (lower-typical) in 97% of curves, $2 \times$ median accurately estimated the 25th percentile (upper-typical) in 95% of curves, and $3 \times$ median accurately estimated the 10th percentile (best-case) in 96% of curves. The accuracy of using simple multiples of the median survival was independent of the duration of median survival.

Table 2 summarizes associations between the characteristics of each trial and its median OS. Longer median OS was associated with using trastuzumab to treat women with HER2-positive tumors, with using taxane-based chemotherapy, and with having a higher proportion of women with ER-positive tumors. The median OS in the two trials of women with HER2-positive tumors receiving trastuzumab was 16.2 months longer than the median OS in the 29 trials of women with tumors of unknown HER2 status not
OS curves were remarkably similar in these trials of first-line chemotherapy for MBC published in the last 10 years. For most of the OS curves, simple multiples of each curve's median provided accurate estimates of its percentiles, corresponding to worst-case, typical, and best-case scenarios. This meant that for most OS curves, the survival time for the 10% of patients in the worst-case scenario could be accurately estimated as about one quarter of its median or less, the survival of the middle 50% of patients (75th to 25th percentiles, typical scenario) was accurately estimated as ranging from about half to double its median, and the survival time for the 10% of patients in the best-case scenario was accurately estimated as about three times its median or more. In these trials of first-line chemotherapy for MBC, the median OS was typically about three times the median PFS. These observations provide a basis for simple rules of thumb that doctors can use to help estimate and explain life expectancy to women with MBC who are starting chemotherapy.

On the basis of prior work, we expected and found that the survival curves in this review were flatter at the ends and steeper in the middle than a true exponential curve, and the less extreme multiples of the median were thus appropriate for estimating the 10th and 90th percentiles.

We expressed the accuracy of using simple multiples of the median to estimate other percentiles of a given survival curve in terms of how often the estimate was within 0.75 to 1.33 times the actual value. This criterion for accuracy is arbitrary but was specified a priori on the basis of clinical judgment and is symmetrical on a logarithmic scale, as is appropriate for a ratio of two values (estimated:observed). Accuracy was lowest for the worst-case scenario in which multiplying the median by 0.25 tended to underestimate survival. This underestimation probably reflects the exclusion from trials of patients with an obviously poor prognosis, for example by requiring a life expectancy of at least 3 months as an inclusion criterion. The simple multiple of 0.25 is probably still reasonable for routine clinical practice in which patients with a shorter life expectancy are not excluded.

This review has important clinical implications. Questions about life expectancy are frequently asked and are difficult to answer, and many patients have a poor understanding of their prognosis. There is ample literature providing guidance on how to communicate about prognosis but little on how to estimate life expectancy. This lack of guidance and information is one of the reasons that has been proposed for doctors’ reluctance to discuss prognosis. On the basis of this review and our previous work, we suggest that questions such as “How long have I got?” are best answered by providing worst-case, typical, and best-case scenarios that are based on simple multiples of the estimated median survival of a group of similar patients.

The ideal source of an estimated median survival for a group of similar patients would be a population-based study of similar patients using similar treatments. In the absence of such ideal data, pertinent clinical trials provide a pragmatic and readily available starting point. However, patients in clinical trials are not representative of those seen in routine clinical practice, so adjustments may be required to account for differences that might influence their outcomes. These adjustments may only need to be small for the majority of patients who would meet all or most eligibility criteria for clinical trials. For example, the distribution of median survival times in this review was quite narrow, with 90% of values falling between 16 and 28 months. Patients with characteristics associated with a poor prognosis, such as brain metastases or poor performance status, are often excluded from clinical trials and would require larger adjustments, or preferably different sources of survival data on which to base their survival estimates. Additional studies are needed to determine how survival data from trials should be adjusted for individual patients.

Although surveys suggest that the majority of patients with advanced cancer want specific information on the best-case, worst-case, and typical scenarios for their survival, patient understanding and
satisfaction when prognostic information is presented this way has not been assessed, and research in this area is needed. Many patients want realism and honesty from their doctor when discussing prognosis but, at the same time, most also want hope and optimism. We believe estimating and explaining typical, best-case, and worst-case scenarios for survival is preferable to presenting a single-point estimate of the median survival and can help clinicians convey realistic hope. The typical scenario is explained as the most likely outcome, representative of the middle 50% of patients. The best-case scenario is less likely, representing the 10% of patients with the best prognosis, but it is still a possible outcome that can be hoped for. This hope is balanced by presenting the equally possible worst-case scenario, which allows the patient to prepare for the worst. Research is needed to test this belief.

We have not attempted to estimate survival from the time of diagnosis of breast cancer or from the time of diagnosis of metastatic disease but acknowledge that these are two other common times for patients to request life expectancy information. The patients in this review will be quite different in terms of their survival time and treatments before beginning palliative chemotherapy, but we have found that after starting chemotherapy, survival times are quite similar.

We found that median OS was about three times median PFS (IQR, 2.4 to 3.5 months), as did Saad et al in their recent review. This is an observation about summary data from groups of patients, but it raises the hypothesis that doubling the observed time to progression might provide a useful estimate of postprogression survival. If corroborated, a rule of thumb based on this observation might facilitate discussion of prognosis after progression on first-line chemotherapy. The relationship between PFS and OS might also be helpful for planning future studies.

This review was not designed to determine individual prognostic and predictive factors in MBC, and individual patient data would be required for this. Prognostic indexes including clinical variables and other measures such as circulating tumor cells can provide more precise information on life expectancy for an individual patient; however, such indexes will never be 100% accurate. Our suggestion to provide patients with estimates for three scenarios could supplement such measures. There will always be best-case, worst-case, and typical scenarios, and it is important to explain these to patients rather than presenting them with a one-point estimate from a prognostic index. It is possible that rules of thumb based on simple multiples could be used to estimate these scenarios from a prognostic index estimate rather than from the median.

We did not seek to determine the most effective first-line treatment for MBC; this would require randomized comparisons. Our indirect comparisons of trial characteristics and survival times raise some interesting hypotheses and may help doctors select the most appropriate reference groups on which to base their survival estimates. The treatments associated with the longest OS were trastuzumab in HER2-positive tumors and taxanes. To improve the accuracy of survival estimates for women about to begin trastuzumab and chemotherapy or taxane-based chemotherapy, we suggest doctors start with an OS curve from a pertinent trial that includes these treatments. Although our observations are interesting, they should not be taken as definitive evidence that trastuzumab or taxanes prolong OS. Other characteristics of the patients, treatments, and trials may be responsible, and data from prospective randomized trials are required for such conclusions. There are more appropriate sources of data for determining the effects of trastuzumab and taxanes on survival. The randomized phase III trial by Slamon et al reported that the addition of trastuzumab to chemotherapy for women with HER2-positive MBC improved median OS by approximately 5 months. The Cochrane meta-analysis of taxanes in MBC reported that taxane-containing regimens significantly prolonged OS; however, when the analysis was restricted to trials of first-line chemotherapy, as in our review, there was no longer a survival benefit.

Trials with a higher proportion of women with ER-positive MBC were also associated with longer median OS. Because these patients were not receiving endocrine therapy and many would have exhausted their options for endocrine therapy, this observation supports ER-positive tumors having a more favorable biology regardless of treatment.

Whether using simple multiples of the median to calculate estimates of scenarios for survival can be applied to other advanced cancers needs to be determined, but we are encouraged by similar results for advanced non–small-cell lung cancer using the same simple multiples (0.25, 0.5, 2, and 3). The accuracy of these rules of thumb will soon be tested by using clinicians’ predictions of survival at baseline in a randomized trial.

The strengths of this review are that it is comprehensive and applies to contemporary treatment for MBC. It provides simple rules of thumb for doctors to use as a basis to estimate survival times. Although survival estimates will need to be adjusted to account for individual characteristics of the patient, tumor, and treatment, such adjustments probably need only be small for the majority of patients.

The main limitation of this review is that it includes only patients in clinical trials who have a better prognosis than patients treated similarly in routine clinical practice. There are few data available on the survival of patients outside clinical trials. We suggest that doctors use median OS from a pertinent clinical trial as a starting point and then adjust that median according to the characteristics of the individual patient at hand. Data on the upper-typical and best-case scenarios were not included in many trials because they were published before these results were mature. This was particularly so in the most recent trials with the longest survival times such as those in women with HER2-positive MBC receiving trastuzumab. Publication of survival outcomes after longer follow-up is needed to provide better founded estimates of long-term survival but, unfortunately, such publications are rare. We did not record information on the durations of chemotherapy used in these trials or on second- or subsequent-line chemotherapy used. These factors may affect OS, but a recent meta-analysis of first-line chemotherapy duration suggests effects on survival time are likely to be modest. Finally, systematic reviews of this sort are unable to estimate the survival benefits attributable to chemotherapy.

Another potential limitation of this review is that the treatments used may not reflect today’s reality, largely because of changes in adjuvant therapy in the last 10 years. Anthracyclines and taxanes are less likely to be used as first-line therapy today because many patients will have received these treatments in the adjuvant setting. Similarly, more targeted treatment options are becoming available and will hopefully lead to longer OS times in subgroups of patients. Even if the median survival times increase with improved treatments, we expect the multiples of the median to remain accurate for estimating scenarios for survival. This is because it was accurate for most of the 78
survival curves in this review, even though the treatments used in each trial varied. To improve accuracy, we suggest that clinicians select an OS curve from a clinical trial in which patients are randomly assigned to receive similar treatment to that being planned for the patient in question and use the median from this curve as the basis for estimating scenarios.

OS distributions from recent randomized trials of first-line chemotherapy in MBC were remarkably similar, approximately exponential, and had a median OS of nearly 2 years, on average. Simple multiples of an OS curve’s median gave good estimates of its percentiles corresponding to worst-case (0.25 times the median), typical (0.5 to 2.0 times the median), and best-case (3.0 times the median) scenarios for nearly all OS curves. Presenting women with estimates for a range of scenarios for survival should provide prognostic information that is more accurate, realistic, and hopeful than a single-point estimate and hopefully easier to understand.

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