

An Update on Randomized Clinical Trials in Breast Cancer

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KEYWORDS

- Breast cancer • Randomized clinical trials (RCT) • Axillary staging
- Lymphadenectomy • Sentinel lymph node (SLN) • Breast conservation therapy (BCT)

KEY POINTS

- Numerous clinical trials reveal new innovations and therapies that continually change the treatment and prevention of breast cancer.
- Earlier trials have changed the standard of care from radical mastectomy to breast conservation therapy and individualized treatment based on tumor-specific biology.
- As research continues and long-term follow-up results become available, updated reviews on randomized clinical trials become exceedingly important in discerning the most effective and oncologically safe therapies to provide optimal outcomes.

INTRODUCTION

In 2016, more than 250,000 women were predicted to be diagnosed with breast cancer. Representing 14.6% of all new cancer cases in the United States, breast cancer is the most common cancer among women. Numerous clinical trials reveal new innovations and therapies that continually change the treatment and prevention of breast cancer. Earlier trials have changed the standard of care from radical mastectomy to breast conservation therapy (BCT) and individualized treatment based on tumor-specific biology. The landmark randomized clinical trials (RCT) in breast cancer were published in the 2002 and 2010 editions of this publication. As research continues and long-term follow-up results become available, updated reviews on RCTs become exceedingly important in discerning the most effective and oncologically safe therapies to provide optimal outcomes. Many of the published RCTs in the last 7 years have focused on decreasing the overtreatment of breast cancer.

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LEVEL IA EVIDENCE: PROSPECTIVE RANDOMIZED SURGICAL TRIALS AND META-ANALYSES IN BREAST CANCER

Litieri S, Werutsky G, Fentiman IS, et al. Breast conserving therapy versus mastectomy for stage I-II breast cancer: 20 year follow-up of the EORTC 10801 phase 3 randomized trial. *Lancet Oncol* 2012;13(4):412–19.¹

Hypothesis

BCT is an oncologically safe treatment of breast cancer.

Published Abstract

Background

The European Organisation for Research and Treatment of Cancer (EORTC) 10801 trial compared BCT with modified radical mastectomy (MRM) in patients with tumors 5 cm or smaller and axillary node-negative or node-positive disease. Compared with BCT, MRM resulted in better local control, but did not affect overall survival (OS) or time to distant metastases. This study reports 20-year follow-up results.

Methods

The EORTC 10801 trial was open for accrual between 1980 and 1986 in 8 centers in the United Kingdom, the Netherlands, Belgium, and South Africa. The trial randomized 448 patients to BCT and 420 to MRM. Randomization was done centrally, stratifying patients by institute, carcinoma stage (I or II), and menopausal status. BCT comprised lumpectomy and complete axillary clearance, followed by breast radiotherapy and a tumor-bed boost. The primary end point was time to distant metastasis. This analysis was done on all eligible patients, as they were randomized.

Findings

After a median follow-up of 22.1 years (interquartile range [IQR], 18.5–23.8), 175 patients (42%) had distant metastases in the MRM group versus 207 (46%) in the BCT group. Furthermore, 506 patients (58%) died (232 [55%] in the MRM group and 274 [61%] in the BCT group). No significant difference was observed between BCT and MRM for time to distant metastases (hazard ratio [HR], 1.13; 95% confidence interval [CI], 0.92–1.38; $P = .23$) or for time to death (HR, 1.11; 95% CI, 0.94–1.33; $P = .23$). Cumulative incidence of distant metastases at 20 years was 42.6% (95% CI, 37.8–47.5) in the MRM group and 46.9% (42.2–51.6) in the BCT group. Twenty-year OS was estimated to be 44.5% (95% CI, 39.3–49.5) in the MRM group and 39.1% (34.4–43.9) in the BCT group. There was no difference between the groups in time to distant metastases or OS by age (time to distant metastases: <50 years 1.09 [95% CI, 0.79–1.51] vs ≥ 50 years 1.16 [0.90–1.50]; OS <50 years 1.17 [0.86–1.59] vs ≥ 50 years 1.10 [0.89–1.37]).

Interpretation

BCT, including radiotherapy, offered as standard care to patients with early breast cancer seems to be justified, because long-term follow-up in this trial showed similar survival to that after mastectomy.

Editorial comments RCTs have established the safety of BCT compared with mastectomy. The National Surgical Adjuvant Breast and Bowel Project (NSABP) B-06 trial compared patients with tumors less than 4 cm undergoing partial mastectomy and axillary node dissection or MRM. At 20 years, there was no difference in OS or disease-free survival (DFS). However, local recurrence was increased in the BCT group compared with the MRM group. Furthermore, results showed ipsilateral breast

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