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## Abstract

Published 02/13/2024

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## The Theoretical Role for Radiotherapy in Patients with Diffuse Large B-Cell Lymphoma: A Secondary Analysis of a Prospective Randomized Controlled Trial

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Lanier C, Razavian N B, Hughes R T (February 13, 2024) The Theoretical Role for Radiotherapy in Patients with Diffuse Large B-Cell Lymphoma: A Secondary Analysis of a Prospective Randomized Controlled Trial. Cureus 16(2): a1204

### Abstract

**Introduction:** The role of radiotherapy (RT) for diffuse large B-cell lymphoma (DLBCL) is unclear. In patients treated with 6 cycles of chemotherapy for limited or advanced DLBCL, indications for radiation are often considered to be bulky disease (7.5 cm +) or extranodal involvement. This is thought to improve progression-free survival by providing a local control benefit given bulk and extranodal disease are risk factors for local progression in the initially involved area. Many trials call into question the actual benefit of RT. Alliance/CALGB 50303 was a randomized phase III trial comparing two chemotherapy regimens for the upfront treatment for DLBCL in which no patients were to receive RT per protocol. Our objective was to assess the theoretical impact of consolidative RT by assessing outcomes of Alliance/CALGB 50303 patients.

**Methods:** This secondary analysis was performed using PET/CT image sets and data from the NCTN/NCORP Data Archive of the National Cancer Institute. Data were originally collected as part of the Alliance/CALGB 50303 (NCT00118209) clinical trial. Of the 524 registered patients, data and image sets for 155 patients were available for analysis. Two investigators measured the largest sites of nodal involvement on each PET/CT and the average of the corresponding measurements for each lesion was calculated—the largest of these values was used for the determination of bulky disease for each patient. Bulk was defined as any nodal site with maximum diameter greater than or equal to the threshold. Thresholds (in cm) examined included: 5, 6, 7, 7.5, 8, 9, and 10. PFS was estimated for patients with versus without bulky disease and compared between groups using the log-rank test.

**Results:** Of the 155 evaluable pre-treatment PET/CT image sets, 135 patients had measurable nodal disease. Fifteen patients who did not complete treatment per protocol and four patients with mediastinal B-cell lymphoma were excluded. Of the 116 analyzed patients, 45% had stage IV disease, 88% had an ECOG performance status of 0-1, and one patient had double-hit lymphoma. IPI score was 0-2 in 62% and 3-5 in 38%. Chemotherapy was R-CHOP in 61 and DA-R-EPOCH in 55. Best response was CR in 84 patients (73%), PR in 30 patients (26%) and SD in 1 (1%). The median follow-up was 5 years and 32 PFS events were observed. Bulky disease was associated with elevated LDH at diagnosis (using 7.5 cm threshold: LDH elevated in 72% with bulky disease v. 40% with non-bulky,  $p < 0.01$ ) and more frequent use of pegfilgrastim (51% v. 31%, respectively,  $p = 0.04$ ). Overall, the 5-year PFS rate was 72.5% (95% CI 64.1-81.4). Using a 7.5 cm threshold, 5-year PFS was 62.7% in patients with bulk versus 79.5% in those without ( $p = 0.14$ ). There were no significant PFS differences ( $p > 0.05$ ) observed between groups at any threshold between 5 and 10 cm. The 5-year OS was 86.4% (95% CI 80.2-93.1); no differences in OS by bulk using any threshold were observed.

**Conclusion:**

In this secondary analysis of a phase III randomized trial of chemotherapy alone for DLBCL, initial bulk was not shown to be significantly associated with PFS or OS calling into question the theoretical benefit of consolidative radiation in this patient population. Prospective data comparing consolidative radiation versus no radiation in patients with initially bulky disease are necessary to determine optimal treatment paradigms in patients with DLBCL.