RESEARCH LETTER

Women's Representation Among Lead Investigators of Clinical Trials in Oncology

With increasing representation of women in medicine, recent efforts have attempted to determine whether women are adequately represented among leaders of academic medicine and published studies.1-3 We studied the representation of female lead authors for oncologic phase 3 randomized clinical trials (RCTs) because trial leadership affects promotion and tenure, prominence in the field, and access to subsequent funding opportunities. We quantified the proportion of RCTs led by women over time and determined factors associated with female corresponding authorship (FCA) among oncologic RCTs.

Methods | ClinicalTrials.gov was queried on November 19, 2017, to identify oncologic RCTs using the following search parameters: other terms, “cancer”; study type, “All Studies”; status excluded, “Not yet recruiting”; phase, “Phase 3”; and study results, “With Results.” This search yielded 1239 trials (Figure). Trials were then screened for cancer-specific, randomized, multiple-arm trials addressing a therapeutic intervention. Those RCTs without primary end point results published in the peer-reviewed literature were excluded. The earliest publication of a trial’s primary end point results served as the primary publication. Two authors independently screened trials and collected data. χ² tests were used to compare proportions across groups, and a linear regression model was used to analyze FCA changes over time with SPSS version 22.0 (IBM). Data analysis was performed in 2018.

Results | Five hundred ninety-eight trials met the inclusion criteria (Figure), with results published between 2003 and 2018. Among all trials, 107 (17.9%) had FCA. We found lower rates of FCA for industry-funded trials (14.4% [n = 67 of 465] vs 30.1% [n = 40 of 133]; P < .001), and higher rates for cooperative group trials (25.9% [n = 48 of 185] vs 14.3% [n = 59 of 413]; P = .001) (Table). By cancer disease site, we observed high FCA rates for breast and head and neck cancer trials, and low FCA rates for gastrointestinal, genitourinary, and hematologic cancer trials. The primary modality tested also correlated with FCA, with high FCA rates for radiotherapy and supportive care trials, and no female corresponding authors for surgical trials. The geographic location of the corresponding author’s institutional affiliation was similarly associated with FCA, with higher FCA rates in the United States than abroad (Table). Finally, we found a significant increase in the FCA rate over time (by year of primary publication, r = 0.527; P = .04), with an annual estimated 1.2% increase in FCA (95% CI, 0.1%-2.3%).

Discussion | We found an overall FCA rate of 17.9% among oncologic RCTs published between 2003 and 2018. The FCA rate increased at an estimated 1.2% annually, echoing data showing an approximate 1.0% annual increase in the number of female academic hematologist-oncologists. However, the absolute FCA rate for these trials is still lower than the percentage of female academic oncologists in this general study period, ranging from 27% in 2000 to 39% in 2015.2

To our knowledge, the present study provides the first report of specific factors influencing RCT female lead authorship. The FCA rate is lower among industry-sponsored trials, possibly reflecting gender biases that are enhanced in the context of industry relationships with academic medicine.4,5 In contrast, cooperative group trials may more effectively promote leadership roles for women. Certain disease sites, treatment modalities, and geographic regions seem to suffer from a greater degree of gender imbalance in trial leadership, findings that were previously unreported in the literature.

The primary limitation of this study is the source of the clinical trials identified. The mandate of ClinicalTrials.gov has shifted somewhat since its debut in 2000.6 Older trials, trials that do not use systemic therapy, and trials without enrollment in or affiliation with the United States may be underrepresented.3 With that in mind, analyses by treatment...
Abbreviation: FCA, female corresponding authorship.

<table>
<thead>
<tr>
<th>Trial/Author Characteristic Associated With FCA</th>
<th>Trials With FCA, No. (%)</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry funding of trial&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Yes</td>
<td>67/465 (14.4)</td>
<td></td>
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<tr>
<td>No</td>
<td>40/133 (30.1)</td>
<td></td>
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<tr>
<td>Cooperative group trial&lt;sup&gt;b&lt;/sup&gt;</td>
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<td>.001</td>
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<tr>
<td>Yes</td>
<td>48/185 (25.9)</td>
<td></td>
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<tr>
<td>No</td>
<td>59/413 (14.3)</td>
<td></td>
</tr>
<tr>
<td>Trial success (primary end point met)&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td>.11</td>
</tr>
<tr>
<td>Yes</td>
<td>45/294 (15.3)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>56/274 (20.4)</td>
<td></td>
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<tr>
<td>Disease site&lt;sup&gt;d&lt;/sup&gt;</td>
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<td>&lt;.001</td>
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<tr>
<td>Breast</td>
<td>36/105 (34.3)</td>
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<tr>
<td>Gastrointestinal</td>
<td>6/76 (7.9)</td>
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<tr>
<td>Genitourinary</td>
<td>5/69 (7.2)</td>
<td></td>
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<tr>
<td>Head and neck</td>
<td>9/23 (39.1)</td>
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<tr>
<td>Hematologic</td>
<td>11/118 (9.3)</td>
<td></td>
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<tr>
<td>Thoracic</td>
<td>11/87 (12.6)</td>
<td></td>
</tr>
<tr>
<td>Modality&lt;sup&gt;e&lt;/sup&gt;</td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Systemic therapy</td>
<td>65/462 (14.1)</td>
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<tr>
<td>Radiotherapy</td>
<td>5/16 (31.3)</td>
<td></td>
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<tr>
<td>Surgery</td>
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<tr>
<td>Supportive care&lt;sup&gt;f&lt;/sup&gt;</td>
<td>37/113 (32.7)</td>
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<td>Country</td>
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<td>.001</td>
</tr>
<tr>
<td>United States</td>
<td>74/329 (22.5)</td>
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<td>Other countries</td>
<td>33/269 (12.3)</td>
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<tr>
<td>World region of corresponding author</td>
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<td>United States</td>
<td>74/329 (22.5)</td>
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<tr>
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<td>Domestic region of corresponding author&lt;sup&gt;g&lt;/sup&gt; (United States only)</td>
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<td>.03</td>
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<td>West</td>
<td>15/58 (25.9)</td>
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<tr>
<td>Northeast</td>
<td>21/112 (18.8)</td>
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<tr>
<td>Southeast</td>
<td>15/44 (34.1)</td>
<td></td>
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</tbody>
</table>

Abbreviation: FCA, female corresponding authorship.

* The χ² test P values are provided.

<sup>b</sup> Industry funding and cooperative group sponsorship were considered independent variables because some trials were both industry-funded and performed through a cooperative group.

<sup>c</sup> Thirty trials were excluded from the analysis of trial success (whether the primary end point was met) because these trials had multiple primary end point questions with mixed results at time of publication.

<sup>d</sup> Analysis by disease site was limited to those studies with a defined single disease site.

<sup>e</sup> Modality addressed the primary intervention as part of the randomization.

<sup>f</sup> Systemic therapy trials, including chemotherapy, targeted systemic agents, immunotherapy, and others, accounted for most trials by modality; they used systemic therapies to improve disease-related outcomes (eg, overall survival, disease-free survival).

<sup>b</sup> Supportive care trials were those where the intervention aimed to reduce disease- or treatment-related toxic effects as the primary end point.

<sup>g</sup> Domestic regions of US corresponding authors were defined by the US Department of Labor Davis-Bacon and Related Acts regions.

Through identification of the factors associated with gender disparities in RCT leadership, we hope that the academic oncology community will work to better understand and address the underlying reasons for such imbalances.

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**Author Contributions:** Drs Ludmir and Holliday had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Ludmir, Miller, Lin, Jethanandani, Holliday.

**Acquisition, analysis, or interpretation of data:** Ludmir, Mainwaring, Miller, Lin, Jethanandani, Espinoza.

**Study supervision:** Ludmir, Holliday.

**Other—review of the literature for publications resulting from oncology clinical trials:** Miller.

**Conflict of Interest Disclosures:** None reported.

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