ELSEVIER

Journal of Clinical Epidemiology 62 (2009) 752−758

Journal of Clinical Epidemiology

Conference abstracts of a new oncology drug do not always lead to full publication: Proceed with caution

Michelle E. Kho[a], Melissa C. Brouwers[b,c,*]

[a]*Program in Health Research Methodology, Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada*
[b]*Program in Evidence-Based Care, Cancer Care Ontario, Ontario, Canada*
[c]*Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada*

Abstract

Background: Conference abstracts, often the first public record of a study, serve as a catalyst to initiate clinical and policy change. On average, 45% of all conference abstracts subsequently appear as full publications; however, the generalizability of this finding to studies of one intervention, in one population, is unknown. Our objectives were to determine the full publication rate of a cohort of abstracts, median time to publication, and predictors of these relationships.

Methods: We included the first 5 years of clinical abstract reports of rituximab for non-Hodgkin's lymphoma (NHL) from American Society of Hematology (ASH) meetings (1997−2001), identified all unique studies, and used electronic databases to identify full publications. We determined the full publication rate, median time to publication, and predictors of these outcomes.

Results: Of 109 abstracts representing 86 unique studies, the publication rate was 52.3% (45, 95% confidence interval [CI]: 41.3, 63.2), and the median time to publication, 1.4 years with 6.8 years' follow-up. Author affiliation with industry (odds ratio [OR] [95% CI] = 4.60 [1.32, 16.08] and presentation type (oral OR = 5.94 [1.31, 26.88], poster OR = 3.39 [1.24, 9.25]; reference, publication in conference abstract book only) independently predicted subsequent full publication in the adjusted analysis. We identified no predictors of time to publication.

Interpretation: We suggest cautious consideration of data from conference proceedings to inform new technology clinical or policy decisions. Future work needs to examine the generalizability of our results to other diseases and technologies.

Keywords: Publication bias; Medical oncology; Societies; Medical; Publishing; Rituximab; Bias; Epidemiology

1. Introduction

Across the lifespan of a clinical study, the conference abstract is one of the first public records of the study, and the conference itself was historically one of the first venues to receive feedback from peers and colleagues [1]. The pressures to incorporate these initial findings from studies of new technologies into frontline care or policy are intense, particularly in cancer. Although including studies from conference abstracts may limit publication bias, their routine use in systematic reviews, clinical practice guidelines, or policy development is controversial, because of the preliminary nature of results, incomplete reporting of key study characteristics, and lack of peer review [2]. These threats are further compounded if subsequent full publication of the studies does not ensue.

Across the medical literature, less than half of all conference abstracts result in a full publication. Scherer et al. conducted a systematic review of several disease conditions and interventions, and traced the proportion of conference abstracts followed by full publication [3]. Of 79 eligible reports representing 30,394 studies, the publication rate was 44.5% for all study designs and 57.5% for randomized controlled trials (RCTs). Factors associated with publication included positive results, RCT design, and oral presentations. Of the published studies, the median time to publication was about 1.5 years. However, most users of evidence are interested in specific interventions, for specific diseases, in specific populations. Therefore, how generalizable are the results from the general case to the specific to inform our decisions?

In new cancer therapies, similar findings indeed emerge. For example, studies of phase I and III research in medical oncology [1,4,5] and in radiation therapy [6] suggest that

* Corresponding author. McMaster University, 1200 Main Street West, MDCL Room 3206, Hamilton, Ontario L8N 3Z5, Canada. Tel.: 905-525-9140 ext. 22862; fax: 905-526-6775.

E-mail address: mbrouwer@mcmaster.ca (M.C. Brouwers).

0895-4356/09/$ − see front matter
doi: 10.1016/j.jclinepi.2008.09.006

What's new?

Key finding

- Of 109 abstracts representing 86 unique studies of rituximab for non-Hodgkin's lymphoma (NHL), the full report publication rate was 52.3%, and the median time to publication was 1.4 years with 6.8-year follow-up.

What this adds to what was known

- On average, 45% of all conference abstracts subsequently appear as full publications; however, the generalizability of this finding for evidence-based clinicians or policy makers who consider studies of one intervention, in one population, is unknown.
- We studied a cohort of conference abstracts of rituximab for NHL; the publication rate was 52.3%.

What is the implication and what should change now?

- We suggest cautious consideration of data from conference proceedings to inform new technology clinical or policy decisions.

publication rates following oncology conferences vary from 56% [6] to 74% [4]. However, even in these studies, where authors examined a specific modality of care, the focus was on many interventions across different cancers, and only one study conducted an adjusted analysis [4]. Evidence users, including clinicians, guideline developers, clinical managers, policy makers, and system leaders, responsible for advancing a quality of cancer care agenda using evidence in a timely and unbiased manner, need to understand the potential risks and benefits of including conference abstracts in a decision-making context. Further, society expects such users to be aware of, receptive to, and reactive toward abstracts from one meeting.

The purpose of our study was to focus on a decision-maker perspective and examine the transition of a new technology from conference to full publication, including the time to publication. Additionally, we sought to identify predictors of subsequent publication and of time to publication. We chose rituximab (Rituxan; Genentech, South San Francisco, CA, USA), a first-in-class monoclonal antibody for non-Hodgkin's lymphoma (NHL) approved by the United States Food and Drug Administration in 1997, as a new technology exemplar and the American Society of Hematology (ASH), clinically regarded as the prominent meeting for hematological oncology, as the source of abstracts.

2. Methods

We identified all clinical studies of people receiving rituximab as a part of their NHL treatment from the 1997–2001 ASH proceedings with the following key words: rituximab, rituxan, mabthera, and IDEC C2B8. We restricted our studies to those of patients with indolent (i.e., follicular) or aggressive (i.e., diffuse large B cell or mantle cell) lymphoma. We excluded studies of stem cell transplant, human cell lines, preparation for radioimmunotherapy, and non-lymphoma–related conditions, as these represent different clinical indications for rituximab. Two raters independently completed study selection and resolved all disagreements by consensus. We calculated the kappa statistic (κ) to measure interrater agreement for study selection [7].

Using intervention, author, and patient descriptions as matching criteria, we determined the number of unique studies from the included abstracts and identified the number of multiple reports. We attempted to match each study with a full publication in the MEDLINE or EMBASE electronic databases as of September 30, 2007, using the same matching criteria as the abstracts, beginning with first author, followed by second and senior authors, as required [8]. If still unable to match the study, we entered the abstract title(s) as a search phrase in the PubMed and Web of Science platforms. We retrieved the full text publication of each matched study. For those studies we were unable to match, we contacted the primary or senior author by e-mail to determine the study publication status. For each potential abstract–full publication match, we read the full publication in its entirety to ensure we identified the same study. We calculated the 95% confidence interval (CI) for the binary proportion of published studies.

We developed a data dictionary and form (available on request) to extract data from each of the abstracts and full publications (where applicable). Data elements included: authors, study design, presentation type, patients enrolled, duration of follow-up, and reported outcomes (e.g., survival, tumor response, adverse events, quality of life [QOL]). We recorded whether any authors were affiliated with industry based on their reported institutional associations. As a measure of abstract reporting, one rater assessed each study against criteria from previously developed abstract quality scores for RCTs [9] and for observational studies [10]. We rated each abstract's author conclusion rating as positive (in favor of rituximab), neutral, or negative using previously developed scales for RCTs [11] and for observational studies [12].

For studies associated with more than one abstract, we developed several strategies to represent the emerging data from each study over time in three areas: outcome reporting, study design, and sample size. At the abstract level, we included all abstracts reporting our outcomes of interest. If one abstract reported on QOL and another on response, we included both abstracts, and attributed the two abstract outcomes to the same study. At the study level, we reported the most robust study design according to the following hierarchy: randomized trial (most robust), nonrandomized comparative study, case–control study, before–after study,