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## Selective outcome reporting is present in randomized controlled trials in lung cancer immunotherapies



Selective outcome reporting (SOR) is a type of in-study publication bias that occurs when only some outcomes listed in trial registries are reported in published articles often to increase the appearance of positive findings [1]. SOR contributes to distorting the scientific literature [2–4]. We investigated the presence of SOR in randomized controlled trials (RCTs) of lung cancer immunotherapies and noted the presence of trial registration, reporting of trial registration numbers, prospective registration, and compliance with CONSORT guidelines.

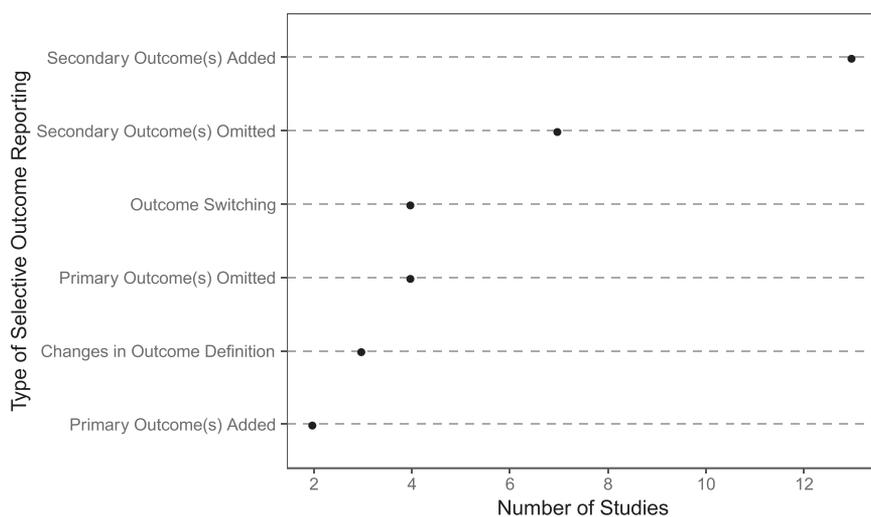
Detailed methods can be found in the [Supplementary Materials \(Appendix 1\)](#) at [www.jclinepi.com](http://www.jclinepi.com). Briefly, we searched MEDLINE and the Cochrane Central Register of Controlled Trials for eligible RCTs. We found corresponding trial registration entries by checking to see if authors reported the registration numbers in the text of their

articles or by hand-searching [ISCRCTN.org](http://ISCRCTN.org). Using Fisher’s exact test, we compared whether the presence of SOR was associated with study significance ( $P \leq 0.05$  vs.  $P > 0.05$ ), prospective registration (yes/no), and funding source (industry/other).

[Supplementary Fig. 1](#) and [Table 1](#) in the Supplementary Materials show the study selection process and study characteristics. Characteristics are also summarized in [Supplementary Fig. 2](#). Of 42 articles that met our criteria, 20 did not report a trial registration number in the text. Overall, we identified 26 trial registrations, 22 on account of reported registration numbers, and four through manual searching of trial registries [5–8]. Ideally, all studies should provide registration numbers in published reports to comply with International Committee of Medical Journal Editors recommendations and CONSORT guidelines [9]; however, individual journals enforce compliance differently [10].

Of 26 articles, 19 had prospective registration, and seven were registered during the trial or after completion, with six of seven articles published before 2013. Twenty-four articles met criteria for SOR analysis; the most common SOR was the addition or omission of secondary outcomes ([Supplementary Table 2](#); [Fig. 1](#) below). Five articles did not have any SOR present [11–15]. Only two of the 24 articles adhered to CONSORT guidelines [7,16]. SOR was found to be associated with study significance ( $P = 0.04$ ), but not prospective registration or funding source ([Supplementary Tables 3–5](#)).

Researchers may alter secondary outcomes more often than primary outcomes because doing so is unlikely to change the primary study question or design. Thus, researchers might believe that a comprehensive list of secondary outcomes is not necessary for trial registration, and subsequent changes to the list do not require updates to the registry.



**Fig. 1.** Types of SOR present in studies ( $n = 24$ ). Note. Summary of the different kinds of SOR present in eligible studies ( $n = 24$ ). Outcome switching refers to either a primary outcome switched to secondary or a secondary outcome switched to primary. SOR, selective outcome reporting.

Our study showed that the use of trial registries in cancer immunotherapy is inconsistent and SOR exists, emphasizing the need for more concern with SOR in this field. The need for initiatives, such as AllTrials and COMPare [17,18], highlights the persistence of SOR in health care research. We advise journal editors to enforce International Committee of Medical Journal Editors and CONSORT guidelines regarding trial registration, reporting of registration numbers in submitted articles, and the need for explanations of outcome switching.

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### Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jclinepi.2018.10.010>.

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