

Letter to the Editor

Dear *Cutis*[®]:

In the Introduction of the February 2003 supplement to *Cutis*, I believe Weiss et al¹ mislead readers in stating, “Two studies indicate that results from open-label observational studies are similar to those reported from randomized controlled trials.”^{2,3} The authors leave out important details from the cited articles (Benson et al and Concato et al).

Benson et al² state “. . . although observational studies may generally give valid results, there are known limitations. . . .” Further, they state “. . . the fundamental criticism of observational studies is that unrecognized confounding factors may distort the results. . . .” Concato et al³ were speaking of observational studies (with either a cohort or a case-control design).

When Weiss et al¹ state “. . . results from open-label observational studies are similar to those reported from randomized controlled trials,” but leave out the details of the citations, they misguide the reader.

Not enough is known about the placebo effect.⁴ Still, acknowledgment and discussion of a possible placebo effect could be addressed in the present study.

Sincerely,
Joel T.M. Bamford, MD
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Author Response

We had no intention of misleading the readers regarding the validity of observational studies. Our intention was to support the use of the observational study design in certain circumstances. Therefore, we cite 2 recent examples that support the usefulness of observational studies and demonstrate that “. . . the results of well-designed observational studies (with either a cohort or case-control design) do not systematically overestimate the magnitude of the effects of treatment as compared with those in randomized, controlled trials on the same topic. . . .”³ or that little evidence supports

that “. . . estimates of treatment effects in observational studies reported after 1984 are either consistently larger than or qualitatively different from those obtained in randomized, controlled trials. . . .”² After further reviewing the statements, we agree that a more complete description of the study by Concato et al³ would clarify that the studies included in their analysis were either of a cohort or a case-control design. However, the overall conclusion of the article by Benson et al² was as stated above. The authors provided full citations to the readers to allow them to further research these issues and were in no way attempting to hide information or mislead anyone. Undoubtedly, we agree that observational studies have limitations, including unrecognized confounding factors.

No placebo was administered during this open-label observational study and therefore, we could not determine any possible placebo effect—a well-known limitation of such studies. Certainly, it is possible that a proportion of patients responded positively to treatment simply because they knew they were applying active therapy.

Sincerely,
Jonathan Weiss, MD
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REFERENCES

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