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Reply

We thank Drs. Bartoletti and colleagues for their interest in our study (1).

If one could operate in a world without risk and that is unconstrained by costs, all incidental findings (IFs) could be investigated. However, the investigation of IFs must be tempered by the reality that benefits may be offset by risks and costs. In this unblinded observational study, mortality was chosen as the primary outcome measure because it is least influenced by subjectivity. Although we agree that when interventions prevent or delay death the mortality in 2 groups will likely favor equivalence, it is also important to recognize that survival benefits may also be attributed to lead-time bias.

We also agree that a longer follow-up duration may have better facilitated appreciation of differences in outcomes between comparison groups, and this limitation has been acknowledged. However, none of the indeterminate IFs became clinically significant. The majority of the patients were followed up until a diagnosis was made or until no further follow-up was recommended (i.e., the IF was deemed benign). Even if inferior outcomes were noted in IF patients, further studies would be needed to explain whether the association is causal or serendipitous, given the benign disposition of IFs.

Most important is the readers' observation that more studies are needed and that a randomized controlled trial of patients with indeterminate IF would be ideal and should be encouraged. However, one must accept that randomizing patients with IFs could be seen as unethical and may not be clinically feasible at many centers. Thus, it is important that results such as ours be used to encourage discussion and to cast doubt on our current clinical practice, thus opening the opportunity for researchers to justify such randomized controlled trials.

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