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Reply to Letter from Rogers, et al JID-2013-0820-Letter

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There is no basis for the assertion by Dr. Rogers and his colleagues that our conclusions were erroneous or affected by the study design. We meticulously studied every patient with basal cell carcinoma or cutaneous squamous cell carcinoma diagnosed over a two-year period at two busy hospitals at our academic medical center. We had excellent follow-up on virtually all patients, and we analyzed patients at the two hospitals separately before pooling them. We could find no evidence that long-term recurrence was lower after Mohs surgery than after excision, even with multiple analyses that adjusted for differences in patient, tumor, and care characteristics. We conclude that any difference in recurrence rates could be determined only in a randomized controlled trial in which similar patients with similar tumors are randomized to receive one treatment or another.

It is clear that for most nonmelanoma skin cancers, there is insufficient evidence-- from our large prospective cohort study and the European randomized controlled trial in facial basal cell carcinomas (Mosterd *et al.*, 2008)--to guide choices between therapies. What this means for our specialty is that we have no data to justify the dramatic increase in Mohs surgery utilization in the US over the last decades given that Mohs surgery is not the less expensive treatment. (Wilson *et al.*, 2012) Because they are costly, randomized controlled trials often are conducted after observational studies demonstrate clinical equipoise in important, targeted situations. This is precisely the situation in which we find ourselves for many nonmelanoma skin cancers. The results of our studies strongly support a focused randomized controlled trial of surgical treatments for nonmelanoma skin cancer, and I urge Dr. Rogers and colleagues, as respected Mohs surgeons and leaders, to join me in supporting this next scientific approach to studying the comparative efficacy of these treatments.

In my experience, arguments against such a trial typically fall into three types. First is the conviction that a trial is not indicated and may be unethical because the result would be obvious, since a therapy that eliminates every visible tumor cell and spares normal tissue will of course be curative and therefore superior. Such a belief is wrong in, for example, prostate cancer, (Wilt and Ahmed, 2013) and the consistency of our findings and those of

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the European study for both clinical (Mosterd *et al.*, 2008) and patient-reported (Chren *et al.*, 2007; Essers *et al.*, 2006) outcomes demonstrates that it may be wrong for basal cell carcinoma and cutaneous squamous cell carcinoma. Second is the perspective that since nonmelanoma skin cancer is typically nonfatal, the care of these tumors is too trivial to warrant further study. In fact, of course, these tumors are a burden for the public health; for example, the Global Burden of Disease study determined that the disability-adjusted life years from nonmelanoma skin cancer are equal to those from melanoma and bladder cancer. (Study, 2013) Finally, apparent pragmatists argue that the cost of a definitive randomized controlled trial would be too great. This perspective seems short-sighted for our specialty, since the care of nonmelanoma skin cancer is a key part of our practices, (Connolly *et al.*, 2012; Rogers *et al.*, 2010) the cost to Medicare is an important health care expense, (Housman *et al.*, 2003) and the potential misuse of health care resources is significant enough to engender substantial scrutiny by regulators. (Elston, 2013)

We in Dermatology should be at the forefront of calls to the NIH and other agencies to address scientifically the gap in evidence to guide care for the most common malignancy. We need a definitive randomized controlled trial to determine the superior surgical treatment for important subgroups of nonmelanoma skin cancers. Only with data can we be confident in the comparative effectiveness of the ‘properly selected skin cancer treatments’ about which Dr. Rogers and his colleagues write.

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