A statistical reanalysis of Brachman et al.'s 1962 study of a human anthrax vaccine

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Abstract

In late 2003, the Brachman et al. (1960, 1962) field study of an earlier anthrax vaccine became the basis for an FDA regulatory determination that the currently licensed vaccine was effective against B. anthracis strains, regardless of the route of exposure. Here, the Brachman et al. (1962) field study is reexamined statistically, analyzing the vaccine's effectiveness as a function of risk levels, levels of vaccination status, types of anthrax infection, mill locations, and two study components (total versus experimental groups). Fisher's Exact Tests were used to compare the vaccine and non-vaccine groups because Fisher's Exact Tests are more accurate than the traditional chi-square tests, especially when cell sizes or probabilities are small. Numerous limitations of the trial were discovered or reaffirmed. Even taking both cutaneous and inhalational anthrax into account, we found that the vaccine's protective effects were not statistically significant ($p < 0.05$) in 75% of the mills studied. We found no evidence for the effectiveness of incomplete vaccinations, although design or reporting flaws in the original study mitigated against finding such evidence. The reanalysis of Brachman et al. (1962) does indicate that the anthrax vaccine may help provide some marginal protection against cutaneous anthrax infection; however, cutaneous anthrax is seldom fatal and usually easily cured with antibiotics. The data do not provide statistically significant evidence of protection against inhalation anthrax. In conclusion, our reanalysis indicates that Brachman et al.'s (1962) data actually fell far short, as had actually been long acknowledged by leading anthrax experts until some time after 1999, of demonstrating the efficacy of the anthrax vaccine in humans, especially with respect to inhalational anthrax infection.

Keywords: Anthrax vaccine, Inhalational Anthrax, Cutaneous Anthrax, Limitations of Research