

8.2 Masking in Lyme Disease Trial

Lyme disease is an infection with a spirochete bacterium acquired from a tick bite. Most patients recover after antibiotic treatment of the acute infection, but some can develop chronic symptoms, or "post Lyme syndrome," one symptom of which can be severe fatigue. The STOP-LD trial {Krupp, 2003} was a randomized, double-blind trial of a long course of IV ceftriaxone (an antibiotic) to treat post Lyme syndrome.

The results section includes:

Masking. At ... 6 months 69% (18/26) of the ceftriaxone vs 32% (7/22) of the placebo group correctly guessed their treatment assignment ($p = 0.004$).

In the discussion they wrote:

"The observation that more of the ceftriaxone than placebo treated groups correctly guessed their treatment assignment could mean that masking [blinding] may have been compromised."

Does the comparison above ($P=0.004$) support the authors' concern that masking may have been compromised? Explain. [Hint: think carefully about what is being compared before answering!]

No. In the treatment group, 69% thought they were getting active treatment. In the control group, as many as 100% - 32% = 68% may have thought they were getting active treatment. (We don't know whether there were just the two options or whether something like "can't tell" was an option.) Comparing the proportions who correctly guessed their treatment means you are comparing the proportion who thought they were on active treatment in one group with the proportion who thought they were on placebo in the other. There is no reason why these should be the same!

That the proportion that thought they were on active treatment in both groups was > 50% also is not surprising. If people in either group improved, they might have thought it was because of treatment. If they had some new symptom they might have thought it was a side effect. In each case, they would be more likely to guess they were on active treatment.