

Clinical Efficacy of Qingke Mixture in Treating Mycoplasma Pneumonia in Children: A Randomized Controlled Trial [Letter]

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Dear editor

We read with great interest the randomized trial by Xie et al evaluating Qingke Mixture plus azithromycin for pediatric Mycoplasma pneumoniae pneumonia (MPP).¹ We would like to comment on several methodological aspects that may influence how the results are interpreted.

First, the trial is reported as double-blind, yet only the experimental group received Qingke Mixture in addition to azithromycin. The control group was not reported to receive a taste- and appearance-matched placebo decoction, and there is no description of measures to mask the characteristic smell and color of the herbal preparation. In pediatric wards such differences are usually obvious to parents and staff and may influence symptom scoring and discharge decisions. A clearly described placebo decoction, together with outcome assessors who are independent of daily clinical care, would better protect against expectation bias.

Second, the primary endpoint, total clinical effective rate, collapses an ordinal composite of radiographic, symptomatic and laboratory criteria into a binary outcome. This composite is not widely used in international pediatric pneumonia trials and may give similar weight to changes that have very different clinical importance. Numerous secondary endpoints were then analyzed without reported control for multiple testing in a relatively small sample. Pre-specifying a small set of patient-centred key outcomes and applying a simple hierarchical ordering or adjusted analysis would make the evidence more robust and easier to compare across studies.

Third, although outcomes were measured at baseline and day 6, the analysis mainly relies on separate between-group comparisons at each time point. For continuous variables, analysis of covariance using baseline values as covariates, or comparison of change-from-baseline, could use the available information more efficiently and provide less biased estimates of treatment effect. For spirometry, the American Thoracic Society and European Respiratory Society statement emphasizes age-appropriate procedures, feasibility reporting and strict quality control in pediatric pulmonary function testing.² The study does not report the minimum age, success rate or age range included in lung function analyses, which makes it difficult to judge how representative these data are for younger children.

Fourth, safety monitoring could be further strengthened in view of the pharmacology of the regimen. Qingke Mixture contains Herba Ephedrae, a sympathomimetic herb with recognized cardiovascular actions and documented toxicology,³ while azithromycin has been linked to a small increase in short-term cardiovascular death in some populations.⁴ In this context, protocolized electrocardiography and systematic assessment of arrhythmias were not reported. Future studies of this combination would benefit from ECG monitoring and longer safety follow-up, especially in children with underlying cardiac or electrolyte abnormalities.

Finally, symptomatic and supportive treatment appears to have been provided according to clinical judgment, and actual use of antipyretics, bronchodilators, nebulized therapies or systemic corticosteroids by group is not shown.

Differences in these co-interventions could partly contribute to shorter symptom duration and hospital stay in the Qingke Mixture group.

In summary, the authors provide encouraging preliminary evidence that Qingke Mixture may enhance response to azithromycin in children with MPP. Addressing the above methodological points would substantially enhance the rigor and relevance of future studies.

Disclosure

The authors report no conflicts of interest in this communication.

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