Here's a pretty straightforward double-blinded randomized controlled trial (RCT). Is it good enough to define the best clinical practice for management of iron deficiency in young children?


Iron deficiency anemia (IDA) is one of the bread-and-butter conditions pediatricians manage. At first glance, it's easy to treat - just give some iron - but of course, nothing is easy in medicine! In particular, nonadherence to medication, often due to unpleasant side effects, is a problem. The authors compared 2 different approaches: use of the traditional oral ferrous sulfate drops versus oral iron polysaccharide complex drops. The latter in theory has better tolerability due to better taste.

Eighty infants 9 - 28 months of age were enrolled, with outcome analysis showing statistically significant improvements in mean hemoglobin increase and in numbers of children with complete resolution of IDA in favor of the old standby, ferrous sulfate drops. Rates of resolution of IDA were 29% for ferrous sulfate and 6% for the iron polysaccharide product, giving a number needed to treat (NNT) of about 4.* Tolerability and adherence slightly favored the iron polysaccharide group but did not reach statistical significance.

So far, pretty good. However, I (and the authors) would argue that these findings might not work exactly the same way in everyday clinical care, and the authors tell us why in their discussion of 4 study limitations.

First, only 1 clinical site was involved, which always raises concerns about the generalizability of results. Second, a lot of these kids had severe anemia, even some requiring blood transfusion. Is that a different patient population than seen in general pediatric practice, which usually deals with milder disease? If so, pediatricians in practice may not see the same results. Third, about a quarter of the subjects didn't complete the planned 12 week follow-up period. Though this was exactly the attrition rate predicted by the investigators before starting the study, it's a large dropout rate and could affect study validity. Finally, like most funded RCTs, the children and families had close follow-up and monitoring by study personnel, a luxury not available in the real world.

In spite of these limitations, the old standby ferrous sulfate didn't fare badly.

*NNT is the reciprocal of the absolute risk reduction, in this case (1/(0.29-0.06)) X 100. Translating to words for the results of the study above, for every 4 infants treated with ferrous sulfate rather than iron polysaccharide, 1 additional infant would achieve complete resolution of IDA. As NNT goes, that's a pretty high return on
investment. (BTW, I'm a little annoyed that the authors and JAMA editors made me calculate this on my own, rather than providing it in the article!)

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