

CREDIBILITY OF SUBGROUP CLAIMS IN HAEMATOLOGY CLINICAL TRIALS

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Background and importance

Interpretation of subgroup analysis is potentially important for treatment decisions in medical practice.

Aim and objectives

The aim of this study is to assess the credibility of subgroup claims in haematology RCT

Material and methods

- **Design:** Systematic review of Hematology phase III RCT
- **Period of study:** January 2013-October 2019
- Claims of subgroup effect were classified: Strong claim, claim of a likely effect or suggestion of a possible effect based on **Sun et al 2009 classification**.
- “the 10 criteria for assessing the credibility of a subgroup claim” by **Sun et al 2012** were applied.

Results

- 98 studies reported **subgroup analyses**.
- 24 RCT reported **46 claims of subgroup effect**.
- 44 were claims for the **primary outcome**
- 34/44 claims for the primary outcome, **met 4 or fewer of the 10 credibility criteria**.

Proportion of claims meeting subgroup criteria for primary outcomes

Criteria	Strong claim (n = 25)	Claim of likely effect (n = 2)	Suggestion of possible effect (n = 17)	Total (n = 44)
Is the subgroup variable a characteristic measured at baseline or after randomisation? *	22 (88%)	2 (100%)	14 (82.35%)	38 (86.36%)
Was the subgroup variable a stratification factor at randomization?	12 (48%)	1 (50%)	2 (11.76%)	15 (34.09%)
Was the subgroup hypothesis specified a priori?	7 (28%)	0	4 (23.53%)	11 (25%)
Was the subgroup effect one of a small number of hypothesised effects tested (</= 5)?	6 (24%)	1 (50%)	10 (58.82%)	17 (38.63%)
Was the interaction test significant (P <0.05)?	10 (40%)	0	8 (47.06%)	18 (40.91%)
Is the significant subgroup effect independent, if they were multiple significant interactions? *	13 (52%)	1 (50%)	12 (70.58%)	26 (59.09)
Was the direction of the subgroup effect correctly prespecified?	0	0	0	0
Was the subgroup effect consistent with evidence from previously related studies?	7 (28%)	1 (50%)	3 (17.65%)	11 (25%)
Was the subgroup effect consistent across related outcomes?	6 (24%)	0	4 (23.53%)	10 (22.72%)
Is there indirect evidence that supports the hypothesised interaction (biological rationale)?	4 (16%)	0	4 (23.53%)	8 (18.18%)

Conclusion and relevance

- Subgroup claims reported in hematology RCT lack of credibility, even when claims are strong.
- Subgroup analysis should be carried out due to the potential information they can provide