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## 发展全科科研 助力全科医疗

——当阴性结果遇上非劣效性试验

对于科研人员来说, 研究结果符合预期当然是最理想的结果, 但实际科研过程中难免遇到研究结果不符合预期、出现阴性结果等。那么, 没有统计学差异的研究结果是否就一定没有意义和价值? 答案是“未必”。

非劣效性试验通常指研究者将一种新疗法与一种标准的有效疗法(非安慰剂对照或空白对照组)进行对照以证实新疗法的疗效不比标准的有效疗法差。预期一种新疗法与标准的有效疗法有效性相似但有某些优势时, 可以采用非劣效性试验。《新英格兰医学杂志》曾发表的一篇文章也指出, 当研究主要结局为阴性时应考虑包括非劣效性试验在内的12个问题(详见<https://www.ncbi.nlm.nih.gov/pubmed/27579636>)。

Moxatag注册试验是经典的非劣效性试验之一, 该试验预期Moxatag口服治疗12岁及以上青少年和成人酿脓链球菌感染所致咽炎和/或扁桃体炎在主要终点细菌清除率方面不劣于penicilin(青霉素)并设定非劣效界值为10%, 结果显示, Moxatag和penicilin细菌清除率分别为85.0%和84.3%, 证实Moxatag和penicilin在细菌清除率方面相差未超过10%; 而在有效性和安全性相当的基础上, 与需要4次/d口服的penicilin相比, Moxatag仅需1次/d口服成为其主要优势, 患者服药方便性和依从性明显提高最终促使美国食品及药品监督管理局(FDA)批准Moxatag作为阿莫西林775 mg缓释制剂上市。

可以说, 非劣效性试验评估的新疗法虽然与标准的有效疗法相近, 但往往还有其他优势, 如不良反应或侵害性更少、价格更低、使用更简便、疗程更短等, 非劣效性试验评估的新疗法之所以会被认可往往也正是基于这些优势。当全科医生在科研过程中利用差异性检验出现阴性结果时, 如果新疗法确有其他方面的优势, 不妨考虑非劣效性试验, 或许会柳暗花明, 出现意想不到的转机。

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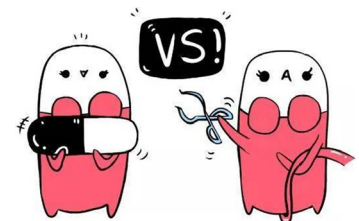
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