Is an RCT still the holy grail?

Gionata Fiorino

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The speaker argues that randomized controlled trials remain the gold standard for generating evidence in IBD, but current trial designs fail to answer key clinical questions due to outdated outcome measures, restrictive inclusion criteria, and reliance on endpoints like the 50-year-old CDAI that may not reflect meaningful clinical improvement.

KEY POINTS

- The speaker stated that all current trials demonstrate any drug is better than placebo for reducing CDAI by 100 points in Crohn's disease and reducing symptoms and colonic lesions in UC, but everything else is secondary endpoints and interpretation.
- The speaker reported that a patient enrolled with CDAI of 399 dropping to 298 meets the current definition of clinical response, illustrating that the 100-point reduction may not represent optimal treatment success.
- Real-world study outcomes are similar to RCT outcomes when the same definitions are used, according to the speaker, suggesting the issue is trial design rather than the choice between RCTs and observational studies.
- Major unanswered clinical questions include how to choose and sequence advanced therapies, how to treat different disease locations, how long to continue advanced therapies, and how much these therapies impact natural history.
- The speaker advocated for moving beyond mild-to-moderate and moderate-to-severe classifications to clear definitions of active disease and remission, incorporating objective inflammation markers and patient-reported outcomes focused on quality of life impact.
- The speaker emphasized that the medical community has a responsibility to change outcome measures and patient selection criteria rather than relying on regulators and drug companies to define study design.

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