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Summary

MUCOSAL HEALING IN ULCERATIVE COLITIS: DEFINITION, TREATMENT TARGET AND CLINICAL ENDPOINTS

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The FNIH Biomarkers Consortium Mucosal Healing in UC Project developed consensus protocols for histologic assessment in ulcerative colitis clinical trials, including optimal biopsy sampling strategies and AI-based scoring tools.

KEY POINTS

- Sampling 2–3 biopsies per colonic region most effectively captured histologic heterogeneity and improved grading reliability, with agreement across histologic indices increasing particularly after the second and third biopsies.
- A prospective study of 153 UC patients found that targeted and random biopsies showed high correlation (ρ = 0.80–0.86), supporting the use of random biopsies in future clinical trials and practice.
- Rectal histologic remission was highly predictive of proximal colonic remission with 93% endoscopic and 88% histologic concordance, supporting assessment limited to rectum in extensive UC with stable disease.
- Two AI tools were developed using 9,652 whole slide images: AIM-HI UC for predicting Geboes Score subgrades (with performance non-inferior or superior to individual pathologists) and IBD Explore for comprehensive classification of tissue regions, cell types, and crypts.
- This multi-sector collaborative initiative addressed the lack of community consensus on defining and measuring mucosal healing in UC, a priority identified by FDA in 2016 draft guidance encouraging histologic evaluation in clinical trials.

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