

## **Development and validation of the “mini index” (mucosal inflammation -non invasive index) for Crohn’s disease on a large prospective pediatric cohort**

**A. Ben Shoham**<sup>1</sup>, M.A. Cozijnsen<sup>2</sup>, B. Kang<sup>3</sup>, B.H. Choe<sup>3</sup>, Y.H. Choe<sup>4</sup>, R.K. Russell<sup>5</sup>, F.M. Ruemmele<sup>6</sup>, J.C. Escher<sup>2</sup>, L. de Ridder<sup>2</sup>, S. Koletzko<sup>7</sup>, J.M. de Carpi<sup>8</sup>, J. Hyams<sup>9</sup>, T. Walters<sup>10</sup>, A. Griffiths<sup>10</sup>, D. Turner<sup>1</sup>

<sup>1</sup>*Pediatric Gastroenterology, Shaare Zedek Medical Center, Israel*

<sup>2</sup>*Gastroenterology, Erasmus MC/Sophia Children’s Hospital, Netherlands*

<sup>3</sup>*Gastroenterology, Kyungpook National University School of Medicine*

<sup>4</sup>*Gastroenterology, Samsung Medical Center*

<sup>5</sup>*Pediatric Gastroenterology, Royal Hospital for Children*

<sup>6</sup>*Gastroenterology, Université Paris Descartes – Sorbonne Paris Cité, APHP- Hôpital Necker Enfants Malades, France*

<sup>7</sup>*Pediatric Gastroenterology, Dr. von Hauner Children’s Hospital, LMU, Greece*

<sup>8</sup>*Gastroenterology, Hospital Sant Joan de Déu, Spain*

<sup>9</sup>*Pediatric Gastroenterology, Connecticut Children’s Medical Center, USA*

<sup>10</sup>*Pediatric Gastroenterology, Hospital for Sick Children, Canada*

Background: Mucosal healing (MH) has become an important therapeutic goal in Crohn’s disease (CD). Repeated assessments by ileocolonoscopy are less feasible, especially in children. The Pediatric Crohn’s Disease Activity Index (PCDAI) does not correlate well with mucosal inflammation. We develop and validate a multi-item index, based on clinical and laboratory parameters, which could reflect MH in clinical trials as well as for clinical practice. Method: We use data from the prospective ImageKids study where children with CD underwent ileocolonoscopy concurrent with clinical and laboratory data. PCDAI items, laboratory tests and FC, were associated with the Simple Endoscopic Score for CD (SESCD) in a multivariate analysis and validated on an independent prospective cohort. We employed a blended clinimetric, judgmental and psychometric mathematical approach. Results: The derivation and validation cohorts included 154 and 86 children, respectively (n=240; age 14.6±2.6 years; SES-CD 7.8±8.2), of whom 24 (16%) and 56 (65%) had MH (i.e. SESC3), respectively. In regression analysis, the stool and weight items of the PCDAI, ESR and FC were associated with SESC. Judgmentally, we removed the weight item and included CRP, to form a weighted categorized MINI index. In the validation cohort the sensitivity, specificity, PPV and NPV of the MINI, using a cutoff of. Conclusions: In children with ileocolonic CD, the MINI-index reflects MH with a good accuracy. The likelihood of MH with a MINI.