May 2012

CLINICAL RESEARCH ALLIANCE
newsletter

CROHN'S & COLITIS FOUNDATION OF AMERICA

Agenda CRA meeting at DDW 2012

Monday, May 21, 2012
Time: 6:30 AM-7:45 AM
Location: Hilton San Diego Bayfront
Room: Cobalt 500

6:30 Breakfast

6:35 Status of the CRA (H. Herfarth, P. Higgins)

Update of CRA Studies

6:45 MERIT-UC (H. Herfarth)

6:55 PIANO (U. Mahadevan)

7:05 PUCCINI (B. Sands)

Presentation of a new CRA study

7:15 The GEM study (K. Croitoru)

7:35 Questions

7:45 Adjourn

Also at DDW:
Uma Mahadevan will present the results of the PIANO study in the

"Distinguished Abstract Plenary"

Monday, May 21, 4–5:30 p.m.

PIANO: A 1000 Patient Prospective Registry of Pregnancy Outcomes in Women with IBD Exposed to Immunomodulators and Biologic Therapy

Uma Mahadevan, Christopher Martin, Robert S. Sandler, Sunanda Kane, Marla Dubinsky, James Lewis, William J. Sandborn, Bruce E. Sands

Introduction: Women with IBD and their physicians have concerns regarding the safety of biologic and immunosuppressant medication use during pregnancy. Data regarding the safety of these medications are sparse due to limited sample size at any one center and lack of uniform data collection methods. We created a prospective cohort of pregnant women at 30 US IBD centers to determine whether the complication rates are higher among women with IBD and their offspring who are exposed to azathioprine (AZA), 6-MP, or anti-TNF agents during pregnancy compared to women with IBD who do not take these medications.

Methods: Pregnant women with IBD were prospectively enrolled and contacted every trimester, at the birth of their baby, and at 4, 9, and 12 months of age. Newborn complications for the first year of life and the mothers' medications, disease activity and complications of pregnancy were recorded. Patients were divided into four groups according to exposure between conception and delivery: Unexposed (no thiopurines or anti-TNF agents); Group A

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PIANO (continued)

(6MP/AZA); Group B (infliximab, adalimumab, certolizumab) and Group AB (both thiopurines and anti-TNF).

Results: 1052 women have been enrolled in the study to date, of whom 797 have completed their pregnancy (Unexposed=337; Group A=265; Group B=102, Group AB=59). There were 33 (4.1%) spontaneous abortions (SAB) and 37 infants with congenital anomalies (CA) (4.6%). The use of thiopurines and anti-TNF agents were not associated with an increase in "any complication", SAB, CA, preterm birth, intrauterine growth retardation, caesarean section, or NICU stays even when adjusted for disease type or disease activity. The majority (72%) of newborns were breastfed. Breastfeeding was not associated with an increase or decrease in infection risk among drug exposures and within each drug category. There was a significant increase in infant infections at 12 months of age in the combination therapy group relative to the unexposed group (Group AB, RR 1.50 (1.08-2.09)). Infant height, weight and developmental milestones, adjusted for disease activity, were similar among infants in all groups at 4, 9 and 12 months of age.

Conclusions: Among infants born to women with IBD, the use of biologics and immunosuppressants was not associated with an increase in congenital anomalies, abnormal newborn growth and development or other complications compared to infants of mothers not exposed to these medications. The increase in infections from 9 to 12 months of age among infants exposed to a combination of immunomodulators and biologics during pregnancy merits further investigation. As drug should no longer be detectable in infants at 9 to 12 months, this finding may suggest dysfunctional immune development. Infants will continue to be followed until 4 years of age to determine whether an increase in infections persists.