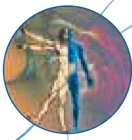


SESSION 5

HOT OFF THE PRESS: CLINICAL TRIALS THAT WILL CHANGE MY PRACTICE NOW!

Risk of Malignancy in Pediatric IBD: Results from the DEVELOP Registry

Hyams JS, Dubinsky M, Baldassano RN, et al. Risk of Malignancy in Pediatric Inflammatory Bowel Disease: Results from the DEVELOP Registry. *Gastroenterology*. 2016 Apr;150(4) Suppl 1:S131.

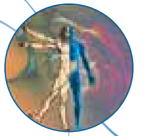
Presented by Anne Griffiths, MD

Results: Lymphoid Malignancies (n=9)

Diagnosis	Age, Gender, IBD dx	Duration of IBD prior to malignancy dx (y)	Duration of IBD therapy prior to malignancy dx (y)				Infectious Exposures
			IFX	ADA	6MP/AZA	MTX	
Acute monocytic lymphoma	17 y M CD	9.2	4	<1	6	3	
Acute lymphocytic leukemia *	16 y M UC	4.5	0	0	0	0	EBV negative
B-cell lymphoma**	16 y F CD	1.6	0	0	2	0	EBV negative
B-cell lymphoma	14 y M CD	7.3	5	3	<1	6	
B-cell lymphoma	18 y M UC	5.1	2	0	0	0	
B-cell lymphoma	22 y M CD	14.1	13	8	6	6	EBV positive
Chronic myeloid leukemia	14 y M CD	3.2	2	0	3	<1	EBV negative
Hodgkin's lymphoma	16 y M CD	4.1	0	0	4	0	
Mycosis Fungoides (Cutaneous T-cell Lymphoma)	13 y M CD	4.1	0	0	3	0	EBV negative

All patients received corticosteroids and/or 5-ASAs , and were not exposed to any other biologic therapies
* This patient was exposed only to 5-ASAs and steroids
**This patient was also diagnosed with HLH

Hyams J., et al. DDW 2016. Presentation 629.



Results: Solid Tumors and Skin Cancers (n=5)

Diagnosis	Age, Gender, IBD dx	Duration of IBD prior to malignancy dx (y)	Duration of IBD therapy prior to malignancy dx (y)				Infectious Exposures
			IFX	ADA	6MP/ AZA	MTX	
Solid Tumors							
Adenocarcinoma Parotid Gland	17 y F CD	3.6	<1	2	<1	0	
Renal papillary cell carcinoma *	20 y M UC	3.4	4	3	4	0	
Skin Cancers							
Basal cell carcinoma	13 y F CD	1.1	<1	0	<1	0	Primary EBV
Basal cell carcinoma	16 y F CD	3.2	0	0	3	0	
Malignant Melanoma	14 y M CD	2.0	2‡	0	1	1	

All received corticosteroids and/or 5-ASAs , and were not exposed to any other biologic therapies
*This patient is deceased

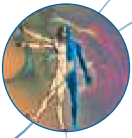
Hyams J., et al. DDW 2016. Presentation 629.

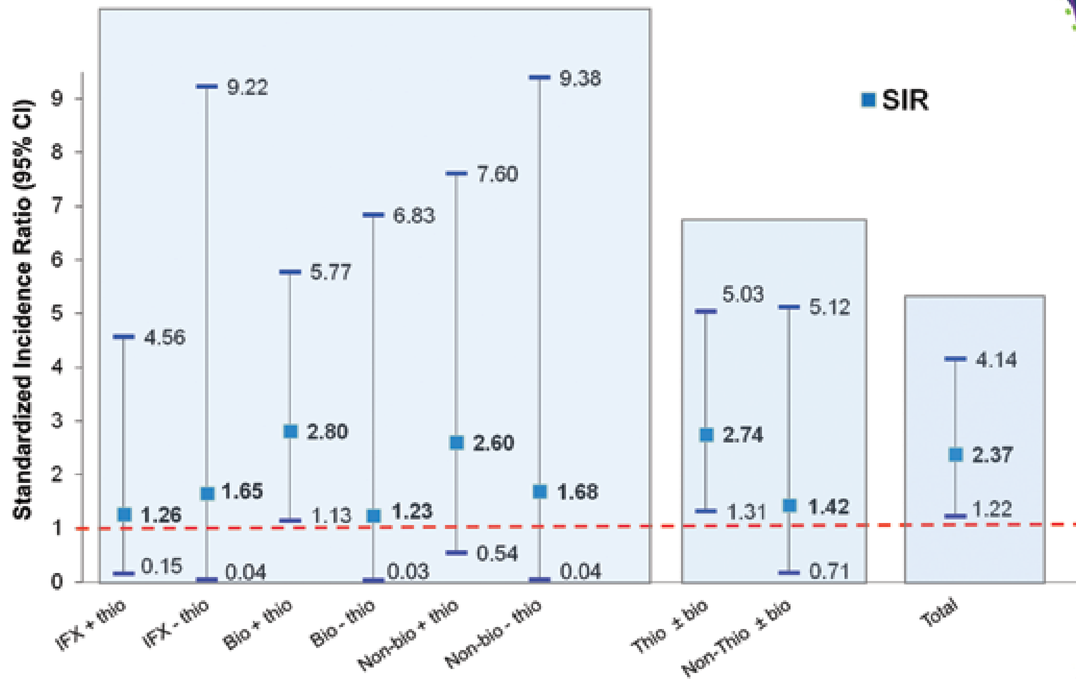
Results: HLH Cases (n=5)

Age, Gender, IBD dx	Duration of IBD prior to HLH dx (y)	Duration of IBD therapy prior to HLH dx (y)				Infectious Exposures
		IFX	ADA	6MP/ AZA	MTX	
16 y F CD	1.2	0	0	1	0	Primary EBV
16 y M CD	11	0	0	11	0	Primary EBV
16 y F CD*	1.6	0	0	2	0	Primary EBV
15 y F CD	1.2	0	0	1	0	CMV**
19 y M CD	7.0	0	0	7	0	Primary EBV

All patients received corticosteroids and/or 5-ASAs, and were not exposed to any other biologic therapies
*This patient was also diagnosed with B-cell lymphoma
** Unknown if primary infection or reactivation of CMV

Hyams J., et al. DDW 2016. Presentation 629.





How will this change practice?

- Further support for the argument that benefit/risk ratio is more favorable for anti-TNF versus thiopurines
- Will raise awareness of HLH with primary EBV infection when thiopurines are used
- Overall more use of anti-TNF (or emerging biologics) in pediatric patients without trial of thiopurines