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...from ACG

Reporting on IBD

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Overview

Introduction: Where are we now

- Biologics
- Safety of Therapy
- Natural History
- Endoscopy in IBD
- Novel Approaches

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Reporting on IBD

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Biologics

- Impact of mucosal healing in Crohn's disease
- Results in ulcerative colitis
- Pharmacoeconomics
- Dosing

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Induction Therapy with Certolizumab Pegol in Patients with Moderate to Severe Crohn's Disease: A Placebo-Controlled Trial

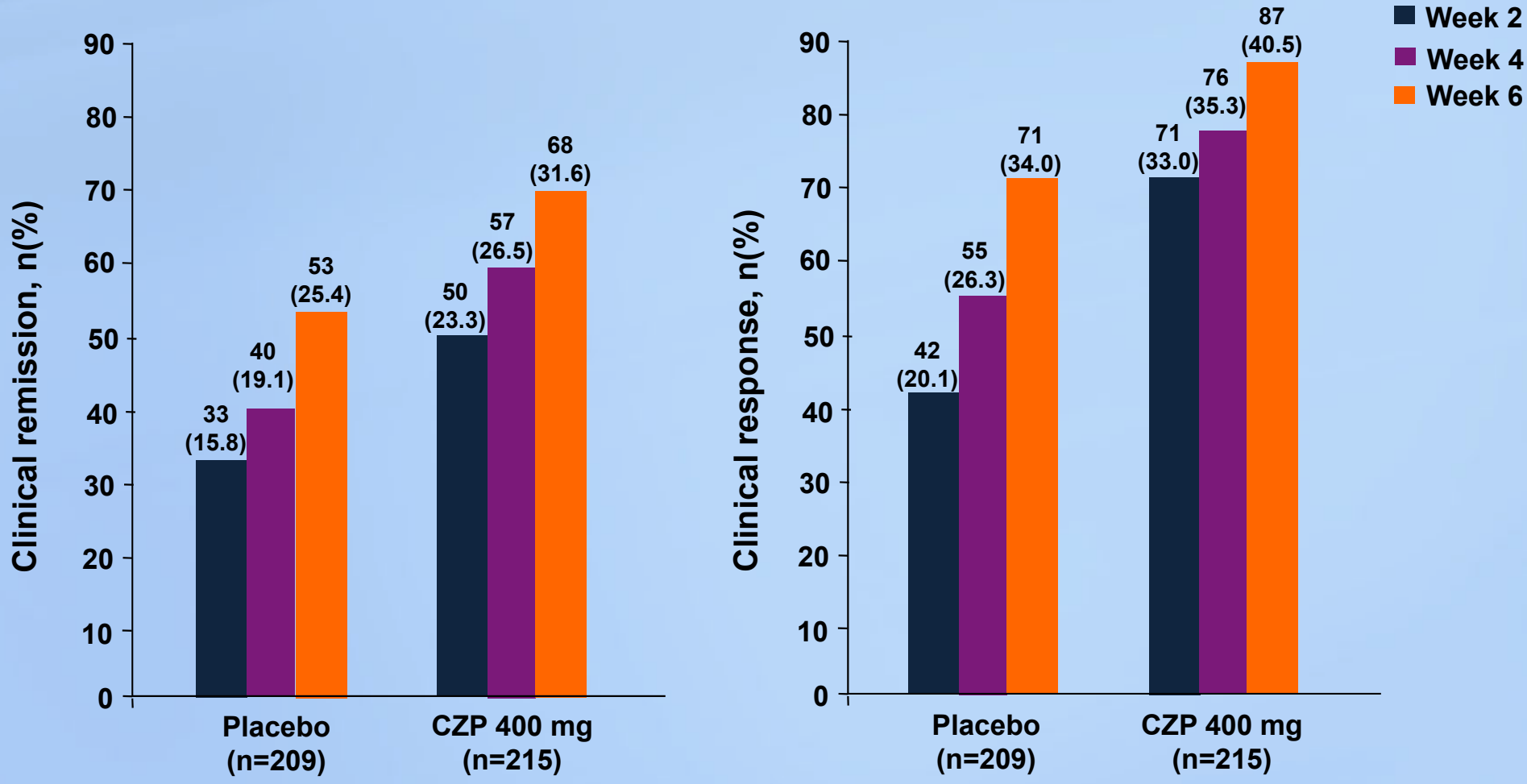
Sandborn W et al. ACG 2010

Methods

- Objective
  - Evaluate efficacy and safety of certolizumab during induction treatment
- Patients
  - Active CD (CDAI 220-450)
- Treatments
  - Certolizumab 400 mg or placebo (weeks 0, 2, 4)
- Primary end point
  - Remission rate (CDAI score ≤150) at week 6
- Secondary end points
  - Response rates (decrease in CDAI score ≥100) at Weeks 2, 4, and 6
  - Remission rate (CDAI score ≤150) at Week 6 in subgroups of patients stratified by the baseline CRP
  - Proportion of patients with adverse events

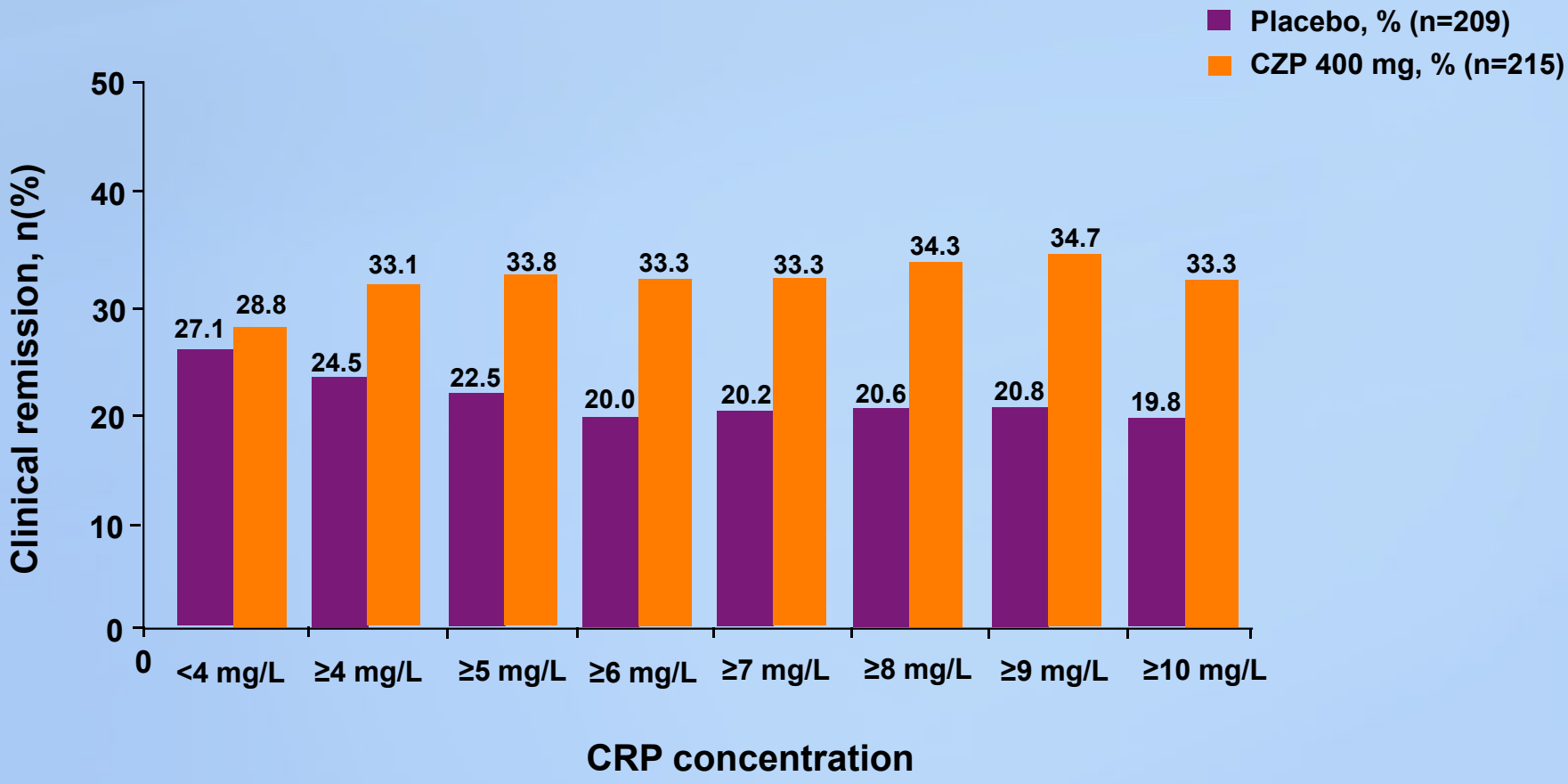
Results

Clinical Remission and Response Rates



Results

Patients achieving clinical remission by baseline CRP



*P<.05

Conclusions

- Induction treatment with certolizumab 400 mg at Weeks 0, 2, and 4 failed to demonstrate a statistically significant increase in clinical remission
- Remission and response rates in the CZP group were numerically greater than placebo at all time points
- CZP showed statistically significant and clinically meaningful superiority vs placebo in patients with signs of active inflammation (baseline CRP ≥5 mg/L)

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Endoscopic Improvement in Patients with Active Crohn's Disease Treated with Certolizumab Pegol: Results of Blinded Central Reading of Recorded Endoscopies from the MUSIC Study (NCT00297648)

Health-Related Quality of Life Improvements in Patients with Active Crohn's Disease Following Treatment with Certolizumab Pegol in the MUSIC Study (NCT00297648)

Hebuterne X et al. ACG 2010

Methods

- Background
  - MUSIC evaluated the effect of certolizumab on endoscopic improvement in moderate to severe CD
- Objective
  - Evaluate endoscopic effects of certolizumab (blinded readings)
  - Assess change in health-related quality of life
- Patients (N=89)
  - Endoscopic disease (ulcerations in ≥2 intestinal segments; CDEIS ≥8 points
- Treatment
  - Certolizumab 400 mg (weeks 0, 2, and 4 and every 4 weeks up to 54 weeks)
- Primary end point
  - Change from baseline in CDEIS score at Week 10 (endoscopy substudy)
  - Change in health-related QoL by IBDQ (quality of life substudy)

Week 10 Endoscopy Results

	Central reading	Local reading
Change from baseline in CDEIS score, mean ± SD	-3.79 ± 4.24 (*P*<.0001)	
Endoscopic response	37%	61%
Endoscopic remission	45%	42%
Complete remission	20%	11%
Deep ulcerations at baseline	77%	92%
Superficial ulcerations at week 10	32%	42%
Complete healing	2%	5%

- Central reading of recorded paired endoscopies confirmed statistically significant improvement in CDEIS scores at Week 10 in patients treated with certolizumab
- Results support initial findings with nonblinded local readings
- In most cases, the central reader was more stringent in interpretation

Results: Health-related Quality of Life

	Week 10 (n=78)	Week 54 (n=50)
IBDQ, mean change (SD)	43.8 (33.8)	44.1 (32.8)
IBDQ response rate (%)	66.3	43.8
IBDQ remission rate (%)	43.8	29.2
IBDQ remission rate in patients **with** endoscopic response	69.7	
IBDQ remission rate in patients **not achieving** an endoscopic response	33.3	

Conclusions

- Central reading of recorded paired endoscopies confirmed statistically significant improvement in CDEIS scores at Week 10
- Treatment with certolizumab resulted in substantial improvement in HRQoL at both 10 and 54 weeks of therapy

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Achievement of Early Deep Remission Predicts Better Long-Term Outcomes for Adalimumab-Treated Patients with Crohn's Disease: Data from EXTEND

Columbel J-F et al. ACG 2010

Methods

- Objective
  - To explore the impact of early deep remission on long-term outcomes in the 52-week EXTEND trial
- Patients
  - Moderate-to-severe ileocolonic CD
- Treatments
  - Open-label adalimumab induction therapy, followed by randomization to adalimumab maintenance or placebo
  - From Week 8, patients with flares/nonresponse could receive open-label adalimumab 40 mg eow (weekly if flares/nonresponse continued)
- Early deep remission was defined as observed mucosal healing + clinical remission (CDAI <150) at Week 12

Key Results

	Deep Remission (Week 12)	
	Yes, % (N=11)	No, % (N=53)
All-cause hospitalization	0	17
CD-related hospitalization	0	9
Week-52 IBDQ remission	64[a]	26
Week-52 SF-36 MCS normal	36	25
Week-52 SF-36 PCS normal	55[a]	19
Week-52 WPAI impairment, LS mean		
Total work productivity impairment	23	44
Total activity impairment	18[a]	43

[a]*P*<.05

Key Results

- Achievement of early deep remission with adalimumab predicted better long-term outcomes in patients with moderate to severe ileocolonic CD

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Effect of Adalimumab Induction Therapy on Clinical Laboratory Parameters Suggesting Improved Nutrition and Inflammation Status in Patients with Moderately to Severely Active Ulcerative Colitis

Reinisch W et al. ACG 2010

Methods

- Purpose
  - Examine the evolution of indicators of nutritional status and inflammation in patients with UC enrolled in a placebo-controlled study of adalimumab for induction of remission
- Design
  - Randomized, double-blind
- Patients
  - Adults with moderately to severely active UC, failing treatment with corticosteroids and/or immunosuppressants
- Treatments
  - Adalimumab 160/80
  - Adalimumab 80/40
  - Placebo

Results

N=521

Change from baseline[a]	Placebo	ADA80/40	ADA160/80
Hemoglobin (g/L)	-0.1	4.4*	4.9*
Hematocrit (fraction)	-0.001	0.014*	0.014*
Red blood cells ($x10^{12}$/L)	0.05	0.16†	0.19*
Total protein (g/L)	0.4	1.5‡	1.7†
Albumin (g/L)	0.7	1.3	1.7†
CRP (mg/L)[b]	-0.10	-0.47	-0.87*

[a]Mean changes, except median change for CRP; [b]Excludes 1 patient without confirmed UC at baseline. *P<.001; †P<.01; ‡P<.05

Conclusions

- Adalimumab was associated with statistically and clinically significant improvements in several nutritional indicators and direct and indirect markers of inflammation

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Reporting on IBD

Adalimumab Induction Therapy Improves Health-Related Quality of Life in Patients with Moderately to Severely Active Ulcerative Colitis

Reinisch W et al. ACG 2010

Methods

- Objective
  - Investigate the effects of adalimumab induction therapy on health-related quality of life (HRQOL) in patients with
- Patients
  - Moderately to severely active UC despite treatment with corticosteroids and/or immunosuppressors
- Treatments
  - Adalimumab (2 regimens)
  - Placebo
- End points
  - Health-related QoL

Key Results: Mean HRQoL Scores Over Time

	Placebo	Adalimumab 80/40 mg	Adalimumab 160/80 mg
IBDQ			
Baseline	125	126	132
Week 4	146	149	163[a]
Week 8	152	153	168[b]
SF-36 PCS			
Baseline	40	41	42
Week 4	43	45[c]	47[a]
Week 8	44	46	49[a]

[a]*P*<.001 vs placebo; [b]*P*<.01 vs placebo; [c]*P*<.05 vs placebo.

Conclusions

- Anti-TNF-naive patients who failed conventional therapy experienced significant improvements in IBDQ and SF-36 PCS scores with adalimumab 160-/80-mg induction therapy
- HR-QOL improvements with the 80-/40-mg induction were inconsistent

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Mucosal Healing in Patients with Ulcerative Colitis Associates with a Reduced Colectomy Risk, High Incidence of Symptomatic Remission, and Corticosteroid-Free State

Sandborn W et al. ACG 2010

Methods

- Objective
  - Assess association between degree of mucosal healing (MH) at week 8 and clinical outcomes in patients with moderate-to-severe UC in ACT1 and ACT2 trials
- Patients
  - Severe UC enrolled in ACT1 and ACT2 trials
- Treatments
  - Infliximab
  - Placebo
- Assessments
  - Mayo endoscopic subscore classification at week 8 (0-normal, 1-mild, 2-moderate, 3-severe disease
  - Time to colectomy through week 54 across the 4 endoscopy subgroups
  - Percentage with symptomatic remission and corticosteroid-free status assessed at week 30 (ACT1/ACT2) and at week 54 (ACT 1 only)

Key Results: Kaplan-Meier Estimates of Time to Colectomy

Randomized to IFX (n=466**)

Week 8 endoscopy score	Number of colectomies	Colectomy-free probability at week 54 (%)	*P*
0 (n=120)	6	95	.0004
1 (n=175)	8	95	
2 (n=114)	14	87	
3 (n=57)	10	80	

**P*-value indicates the difference in distributions of time to colectomy among the 4 endoscopy score subgroups
***Patients who had a colectomy or discontinued before week 8 were not included

- Infliximab patients with lower endoscopy scores at week 8 were more likely to be in symptomatic remission at week 30 (*P*<.0001)
- Patients previously receiving corticosteroids were more likely to be corticosteroid-free at wk 30 as their degree of mucosal healing improved at week 8 (*P*<.0001)

Conclusions

- Patients with moderate-to-severe UC, who achieve early mucosal healing, are less likely to go on to colectomy through 1 year of follow-up
- Improved endoscopic outcomes were associated with a greater likelihood of achieving symptomatic remission and eliminating corticosteroids

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Comparison of Medical Costs Among Patients Using Adalimumab and Infliximab: A Retrospective Study (COMPAIRS)

Sussman D et al. ACG 2010

Methods

- Objective
  - compare health care utilization and costs using insurance data for patients with CD newly initiated on anti-TNF therapy with adalimumab or infliximab
- Design
  - Patients with ≥2 diagnoses of CD who initiated therapy were identified from an electronic database
  - Adalimumab and infliximab groups were matched 1:1 using a propensity score stratified by age, residence, inpatient visit utilization, and steroid use at baseline
- Primary end points
  - 6-month direct cost of health care
- Secondary end points
  - The secondary endpoints compared health care utilization between groups

Mean Health Care Costs/Person During 6 Months After Initiating Anti-TNF Therapy

	All-Cause		CD-Related[a]	
	ADA (N=623)	IFX (N=623)	ADA (N=623)	IFX (N=623)
Anti-TNF drug costs	—	—	10,709	12,401
Other prescription drug costs	1334[b]	1639	546	857
Medical service-related costs[c]				
Hospitalization	3357	5166	3257	4961
Outpatient visit	2482[b]	4565	1579[b]	3659
Total medical service-related costs	6842[b]	10,316	5199[b]	9059
Total health care costs	18,885[b]	24,355	16,454[b]	22,316
Total health care costs, excluding anti-TNF agents	8176[b]	11,955	5745[b]	9916

[a]Based on diagnosis of CD or related comorbidities (eg, malnutrition, anemia, abdominal symptoms, etc);
[b]*P*<.0005 vs. IFX; [c]Medical costs other than hospitalization and outpatients visits are not shown

Conclusions

- In this real-world analysis of patients with CD who newly initiated with ADA or IFX, ADA-treated patients had significantly lower health care costs. Hospitalization and ED utilization were similar between groups

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Higher Weight-based Doses of Adalimumab Reduces Risk of Surgery at 6 Months

Taunk R et al. ACG 2010

Methods

- Background
  - Weight is an important factor in inducing remission in CD
  - Induction regimens with a higher mg/kg dose may result in decreased need for surgery
- Design
  - Retrospective analysis of COBI database of patients treated with anti-TNF therapies
- Primary end point
  - Need for surgical intervention at 6 months by dosage

Results

- Results
  - 58 patients included in analysis
  - Range of adalimumab dosing was 1.73-7.8 mg/kg
  - An association existed between lower adalimumab concentration during induction and need for surgical intervention at 6 months (OR 0.49, 95% CI: 0.28 - 0.84)
  - Significant in both univariate and multivariate analysis (*P*=.009)

Conclusions

- A weight-based regimen may optimize dosing of adalimumab
- Heavier patients may warrant higher induction dosing given a likely lower serum concentration

Biologics: Summary

- Mucosal healing can be achieved and results in improved outcomes
- Anti-TNF therapy can be effective in UC and translates into improved colectomy outcomes
- Dosing is critical for each agent

Safety of Therapy

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Hepatitis B Virus Immunity in Pediatric Patients on Biologics for Inflammatory Bowel Disease: Results of a Prospective Cross-Sectional Study

Moses J et al. ACG 2010

Methods

- Objective
  - Determine hepatitis B immunity and prior exposure in children with IBD on infliximab therapy for IBD
- Patients
  - Pediatric IBD patients on infliximab (N=100)
- Methods
  - Prospective cross-sectional, single-center study
  - Serologic specimens tested for HBsAg, anti-HBc, and anti-HBs
  - Patients with an anti-HBs level ≥10 mIU/mL were considered to be immune

Results

- No patients were positive for HBsAg or anti-HBc
- Regardless of vaccination history, 49% had immunity to HBV (anti-HBs ≥10 mIU/mL)
- Previous vaccinations
  - 91% received HBV vaccination in the past
  - Protective antibodies were absent in 54% of vaccinated patients
- Lower albumin levels and presence of pancolitis were associated with loss of HBV immunity
  - For each 0.5 g/dL decrease in albumin levels, the likelihood of losing immunity increased by 62%
- The concurrent use of infliximab did not affect HBV immunity

Conclusions

- Only half of the pediatric IBD patients had protective anti-HBs levels
- Patients with IBD treated with infliximab without protective immune status against HBV may acquire HBV if they are exposed
- Checking HBV immunity in children with IBD should be strongly considered when patients are started on therapy with infliximab
- Children may need to be boosted when disease improves

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Does Immunosuppressive Therapy Increase Operative Morbidity in Patients with Crohn's Disease?

Bafford A et al. ACG 2010

Methods

- Objective
  - Examine the impact of immunosuppressive therapy on the morbidity of intestinal surgery in patients with CD
- Design
  - Retrospective database review (1999-2010)
- Outcomes
  - Effect of perioperative immunomodulation on anastomotic complications

Results

- 237 intestinal procedures were performed in 214 patients
  - 24.5% were conducted in patients who received more than one immunomodulating medication perioperatively
- 35 complications (17.9%), including 20 (10.2%) anastomotic complications,
- Steroids, 6-MP, anti-TNF agents, and combination therapies did not increase morbidity (*P*=.8)

Conclusions

- Single agent and combination immunosuppressive therapy given within 90 days of intestinal surgery did not increase the incidence of surgical complications in patients with CD

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Update: Meta-Analysis of Overall Risk for Lymphoma with Immunomodulators for Inflammatory Bowel Disease

Kotlyar D et al. ACG 2010

Methods

- Background
  - A previous meta-analysis suggested 6-MP and azathioprine increase risk for lymphoma approximately 4-fold in patients with IBD
  - This study is limited in that referral data was combined with 1 population-based study
  - The risk of lymphoma in referral centers may be artificially inflated due to sicker patients with more comorbidities
- Objective
  - Assess the risk of lymphoma in IBD patients receiving 6-MP or azathioprine
  - Evaluate for referral bias
- Methods
  - Updated meta-analysis including Armstrong 2010

Results

- There were 418 citations, and 412 were excluded. Two studies (Korelitz and Kinlen) were obtained from references from Kandiel 2005, and Lewis 2001 was replaced by Armstrong 2010 as data were also from the GPRD database.
- In referral centers (n=6), the SIR = 4.66. (95% CI: 2.60-7.70).
- In population studies (n=2), the SIR = 4.36 (95% CI: 2.69-6.67).
- Overall the SIR was = 4.48 (95% CI: 3.13-6.20).
- Data from referral centers showed significant heterogeneity (p =0.047), with one study having a very high SIR and one study not observing any lymphomas.

Results: Referral Center Studies

Referral Center Study	Observed	Expected	SIR	95% CI	N
Connell	0	0.52	0	NA	755
Farrell	2	0.05	37.5	3.53-138	238
Fraser	3	0.65	4.64	0.87-13.7	626
Kinlen	2	0.16	12.5	1.18-46.0	321
Korelitz	3	0.61	4.91	0.93-14.5	486
Van Domselaar	5	1.23	4.07	1.28-9.56	345
Combined	15	3.22	4.66	2.60-7.70	2771

NA=Not applicable; CI=confidence interval; SIR=standardized Incidence ratio

Results: Population-based Studies

Population Based Study	Observed	Expected	SIR	95% CI	N
Armstrong	4	1.24	3.23	0.84-8.34	1955
Beaugerie	17	3.58	4.75	2.76-7.62	8676
Combined	21	4.82	4.36	2.69-6.67	10,631

CI=Confidence interval; SIR=Standardized incidence ratio

Overall Results

Overall Data	Observed	Expected	SIR	95% CI	No. of pts.
All studies	36	8.04	4.48	3.13-6.20	13,402

CI=confidence interval; SIR=standardized Incidence ratio

Conclusions

- Patients with IBD who are treated with thiopurines have approximately a 4- to 5-fold increased risk of lymphoma as compared to the general population
- The estimated magnitude of this increased risk is similar in studies from referral centers and in population-based studies.

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The Influence of Anti-TNF Therapy on the Course of Chronic Hepatitis C Virus (HCV) Infection in Patients with Inflammatory Bowel Disease (IBD)

Lin M et al. ACG 2010

Methods

- Objective
  - Analyze impact of anti-TNF treatment on the course of chronic HCV infection in patients with both IBD and HCV infection
- Methods
  - Retrospective database review
  - Patients with a diagnosis of both IBD and HCV infection were identified
  - Data assessed for demographics, duration of IBD and HCV infection, HCV RNA levels, HCV genotype, liver histology, hepatic biochemical tests (HBT) and IBD disease activity

Results

Five patients with HCV and receiving infliximab. Patient demographics and disease characteristics

Patient	Gender	Age (yrs)	IBD Sub type	Duration of IBD (yrs)	Duration of HCV (yrs)	Infliximab Therapy (yrs)	Geno -type	Liver Histology (stage)
1	F	64	CD	46	1	4	N/A	1
2	M	56	UC	5	10	3	N/A	2
3	F	72	UC	7	1	1	1	Minimal
4	M	50	UC	9	8	3	1a	4
5	F	85	UC	64	50	0.5	N/A	N/A

Results

Hepatic biochemical tests, viral load and IBD disease activity score before (B) and after (A) anti-TNF therapy

	AST (u/L)		ALT (u/L)		ALP (u/L)		Viral load (IU/mL)		IBD Disease Activity Score	
Patient	B	A	B	A	B	A	B	A	B	A
1	24	24	23	14	56	61	891	N/A	8	5
2	28	18	39	16	129	145	2,172,660	2,400,000	9	2
3	35	33	34	22	86	73	2,786,118	2,128,414	5	1
4	49	109	35	51	43	72	11,000,000	6,838,000	7	4
5	100	46	145	41	125	114	10,900,000	N/A	9	8

- Treatment of IBD with infliximab in HCV patients did not result in hepatic biochemical tests flares while there was an improvement in the IBD disease activity score.

Conclusions

- Treatment of IBD with infliximab in HCV pts did not result in hepatic biochemical tests flares while there was an improvement in the IBD disease activity score
- Results should be interpreted with caution due to the small number of patients studied

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Use of Anti-TNF Therapy is Associated with Decreased Utilization of Diagnostic Imaging and Radiation Dose in Crohn's Disease

Patil S et al. ACG 2010

Methods

- Background
  - CD patients may be exposed to high amounts of radiation from diagnostic imaging in their lifetime, increasing risk for malignancy
- Objective
  - Evaluate impact of anti-TNF agents on radiation exposure
- Patients (N=60)
  - On anti-TNF therapy with ≥1 year of follow up
- Design
  - Number of diagnostic tests and cumulative radiation dose used the year prior and year after anti-TNF were compared

Results

	Year prior to anti-TNF	Year after anti-TNF	*P*
Imaging tests (overall)	5.6±4.8	4.0±7.9	.0002
CT exams	3.2±2.8	1.3±2.6	<.0001
Fluoroscopic exams	0.48±0.8	0.17±0.5	.01
Radiation dose (mSy)		-17.6±25.4	<.0001
Radiation dose from CT (mSy)		-16.5±22.1	<.0001

Conclusions

- The number of diagnostic imaging tests and radiation dose is decreased the year after anti-TNF therapy is initiated
  - Largely explained by decreased use of CT
- These differences may be the result of improved disease activity and reduced disease complications after treatment
- Results may be biased
  - Patients about to initiate anti-TNF therapy are more likely to undergo an extensive diagnostic evaluation

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Natural history of disease

Endoscopy in Inflammatory Bowel Disease

Novel Approaches

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Long-term Maintenance Treatment with MMX Mesalamine in Patients with Quiescent Ulcerative Colitis: Time to Clinical Recurrence

MMX Mesalamine for the Treatment of Quiescent Ulcerative Colitis: Assessment of Symptoms Over 12 months' Treatment

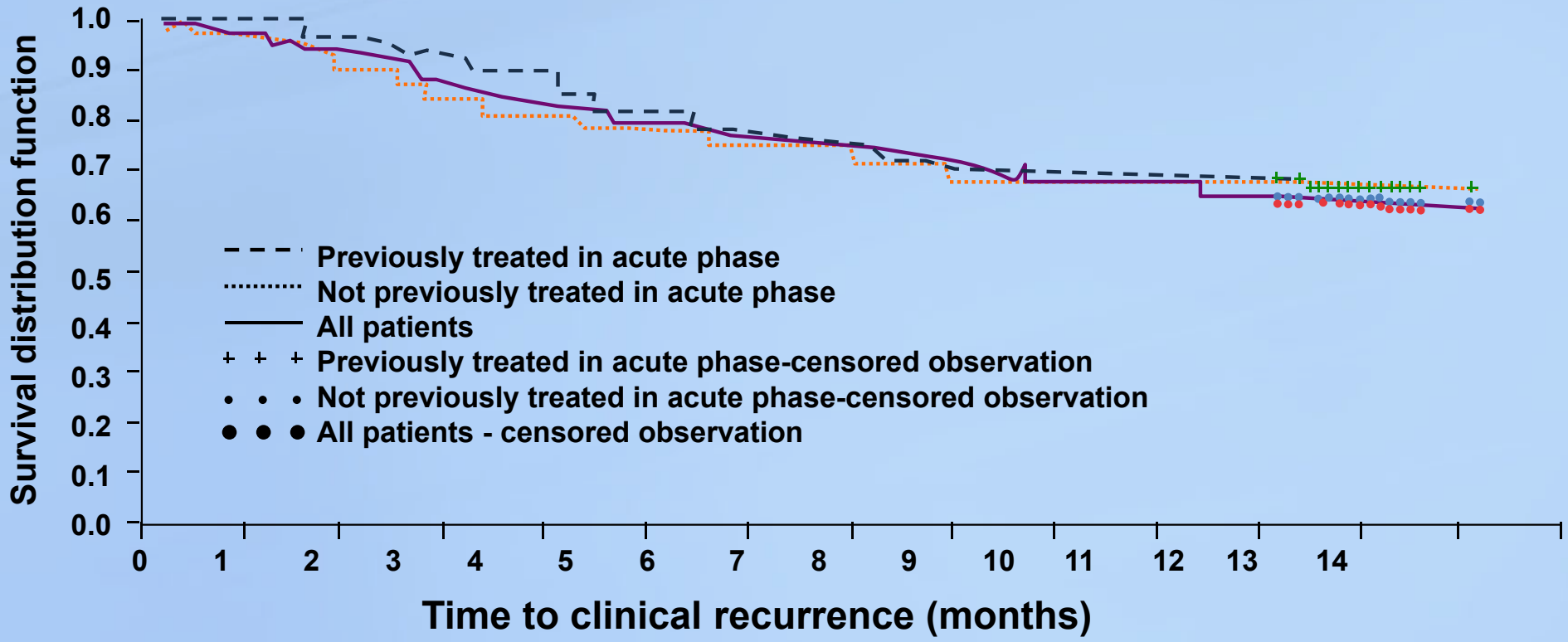
Kane S et al. ACG 2010

Methods

- Objectives
  - Evaluate time to clinical recurrence in patients receiving maintenance treatment with MMX mesalamine
  - Examine efficacy of MMX mesalamine in maintaining disease quiescence in patients receiving long-term treatment
- Design
  - Phase IV, multicenter, open-label trial conducted in 51 US centers
- Patients
  - Quiescent UC at enrollment or after 8 weeks of treatment with MMX mesalamine (2.4-4.8 g/d in acute phase)
- Treatments
  - MMX mesalamine 2.4 g/day once daily for 12 months

Results: Recurrence-Free Rate at 12 Months

64% of patients remained recurrence-free at 12 months



- A low proportion of patients experienced disease recurrence during the study
- Time to recurrence was similar regardless of whether patients had achieved disease quiescence prior to receiving MMX mesalamine therapy or if they first required acute induction therapy with MMX mesalamine

Results: Assessment of Symptoms Over 12 Months

	n (%)	
Symptom	**6 months (n=207)**	**12 months (n=207)**
Frequency of bowel movement	127 (61.4)	105 (50.7)
Rectal bleeding	137 (66.2)	117 (56.5)
Urgency	121 (58.5)	99 (47.8)
Pain	128 (61.8)	110 (53.1)

DO U THINK THIS MEANS THAT THIS PERCENT OF PATIENTS KEPT A SCORE OF 0 IN EACH OF THESE CRITERIA?

Conclusions

- A low proportion of patients experienced disease recurrence during the study
- Time to recurrence was similar regardless of whether patients had achieved disease quiescence prior to receiving MMX mesalamine therapy, or if they first required acute induction therapy with MMX mesalamine

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Vitamin D Deficiency and Abnormal DEXA Scans in Inflammatory Bowel Disease Patients

Abraham B et al. ACG 2010

Objective

- Background
  - There is a high prevalence of osteoporosis in IBD
  - Vitamin D deficiencies have been reported in IBD; prior studies have been conflicting in its association with bone density
- Objective
  - Determine the association between vitamin D deficiency and abnormal bone density in IBD patients
- Methods
  - Prospective study
- Patients
  - Children and adults between the ages 10 and 70 of whom were diagnosed with IBD participated in the study between 2008 and 2010

Results

- Reduction in bone density with a diagnosis of either osteopenia or osteoporosis was found among 22%
  - 50% were aged <40 years
- Patients with an abnormal BMD had significantly higher rate of vitamin D deficiency than those who had normal DEXA scans (40%. vs. 1%; *P*=.001)
  - Association remained after controlling for corticosteroid intake and age
  - Consistent among females and males, independently
- CD patients had a higher rate of abnormal bone density exams compared with UC patients (34% vs 13%; *P*=.02)

Conclusions

- Abnormal bone density is common among our IBD patients with Vitamin D deficiency irrespective of age, gender, or corticosteroid use

XPERT PERSPECTIVES

...from ACG

Reporting on IBD

Ganciclovir is Ineffective at Reducing Colectomy Rate in Inflammatory Bowel Disease in Patients with Superimposed Cytomegalovirus Infection

Alzafiri R et al. ACG 2010

Methods

- Objective
  - Determine effect of CMV antiviral therapy on outcome in patients with refractory IBD and CMV infection
- Design
  - Retrospective analysis of pathology reports of patients with CMV complicating IBD

Results: Colectomy and Death Rates

	CMV cases (N=35)		
	Ganciclovir treated (n=12)	Not treated (n=23)	P
Colectomy (%)	25	34.8	NS
Deaths (%)	5.7	0	NS

Conclusions

- In UC and colonic CD patients, histologically confirmed CMV, especially high intensity was associated with increased severity of disease and colectomy rates
- Use of ganciclovir did not reduce rate of colectomy or death
- The findings support that CMV co-infection should be thoroughly ruled out in severe cases of IBD

Endoscopy in Inflammatory Bowel Disease

XPERT PERSPECTIVES ...from ACG

Reporting on IBD

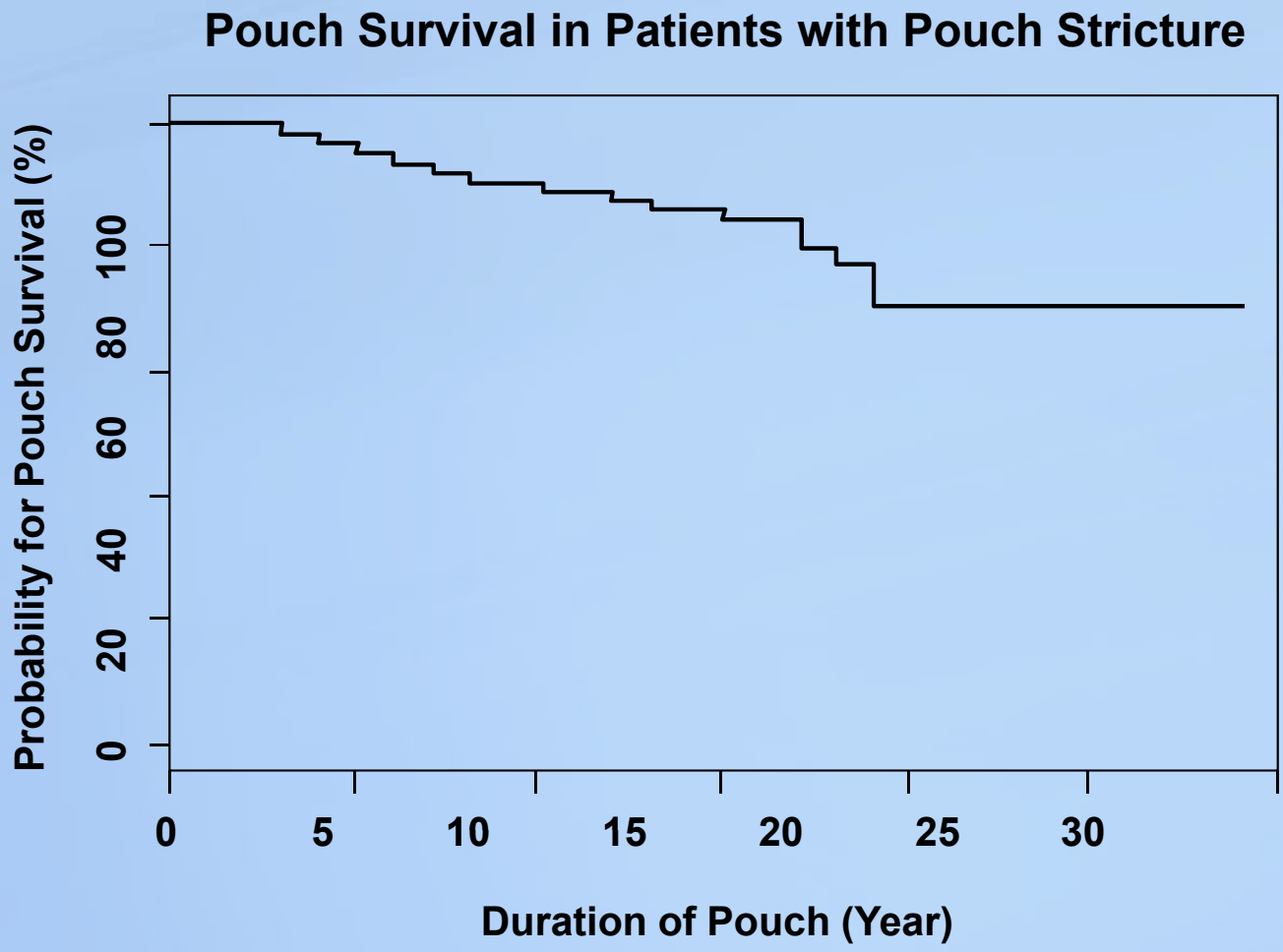
Safety and Outcome of Endoscopic Therapy for Ileal Pouch Strictures

Shen B et al. ACG 2010

Methods

- Objective
  - Evaluate endoscopic balloon dilation and needle knife therapy of pouch strictures with pouch patients with or without CD
- Patients
  - Consecutive pouch patients from single clinic who underwent non-fluoroscopy-guided outpatient endoscopic therapy
  - A total of 150 pts
- Design
  - All procedures were performed by a single endoscopist
  - All underwent endoscopic dilatation (646) , a subset had knife therapy

Results: Pouch Survival in Patients With Pouch Stricture



- Median follow-up: 9.6 (6-17) years
- 19 patients (12.7%) developed pouch failure

Results: Risk Factors for Pouch Failure in Patients with Strictures

Results: Risk Factors for Pouch Failure in Patients with Strictures

Variable	Hazard Ratio (95%CI)	*P*
Number of strictures	1.69 (1.07-2.68)	.02
Cumulative frequency of stricture dilatation	0.95 (0.87-1.04)	.25
Number of pouchoscopies	1.08 (0.9-1.3)	.41
Degree of stricture	1.22 (0.59-2.5)	.59
Balloon size	0.82 (0.64-1.05)	.12
Final pouch diagnosis (CD or surgical complications)	1.61 (0.99-2.61)	.05

Conclusions

- Endoscopic treatment of pouch stricture is safe and efficacious, by improving pouch survival. Underlying diagnosis of CD of the pouch and surgery-related strictures, multiple strictures are the risk factors for pouch failure.

XPERT PERSPECTIVES

...from ACG

Reporting on IBD

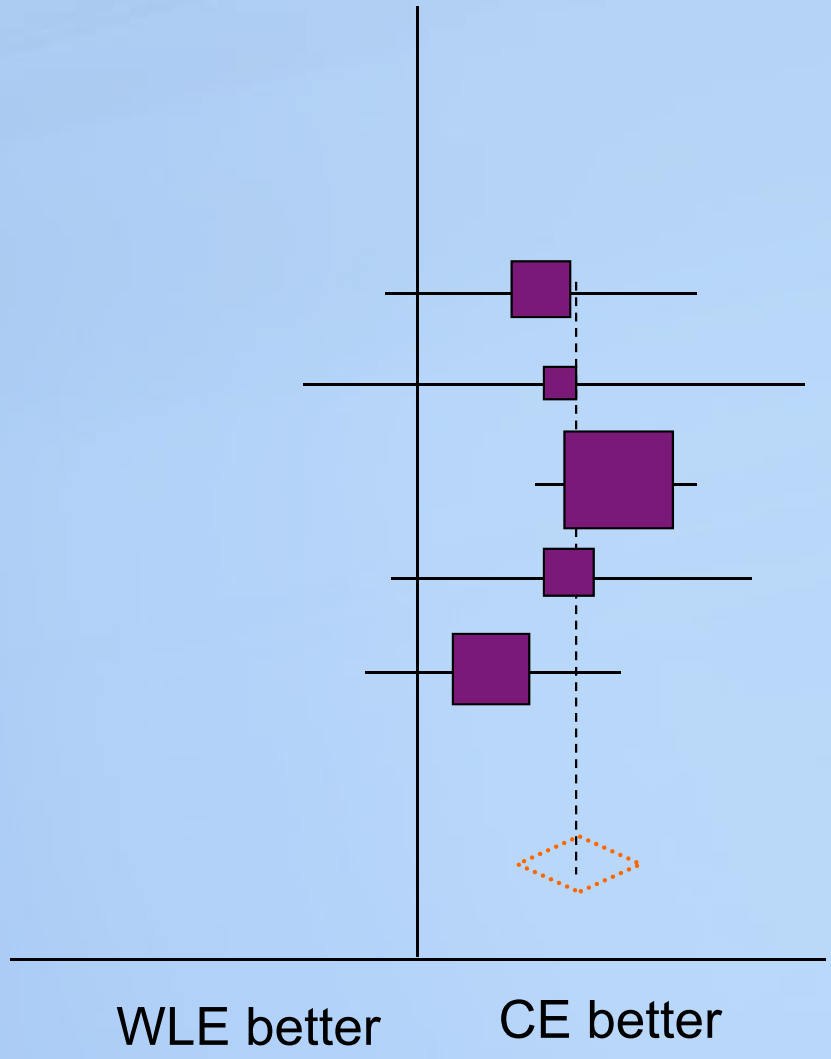
Does the Dye-based Chromoendoscopy Improve Dysplasia Detection in Patients Undergoing Surveillance Colonoscopy for Long term Ulcerative Colitis (UC)? Meta-analysis

Buchner A et al. ACG 2010

Methods

- Objective
  - Compare the diagnostic yield of CE vs white light colonoscopy (WLE) for dysplasia during surveillance colonoscopy
- Methods
  - Literature review and meta-analysis
  - Pooled estimate of OR for the association between CE/WLE and dysplasia detection calculated with random effects models

Results



Conclusions

- This study represents the first meta-analysis of the role of CE in detecting dysplasia during surveillance colonoscopy in pts with long term UC
- Confirms an overall significant benefit of the CE for the detection of dysplasia in flat mucosa and in targeted biopsies
- Does not demonstrate a benefit in detecting dysplasia in visible, raised (“polypoid”) mucosal lesions

Novel Approaches

XPERT PERSPECTIVES ...from ACG

Reporting on IBD

Briakinumab (Anti-interleukin 12/23p40, ABT874) for Treatment of Crohn's Disease (CD)

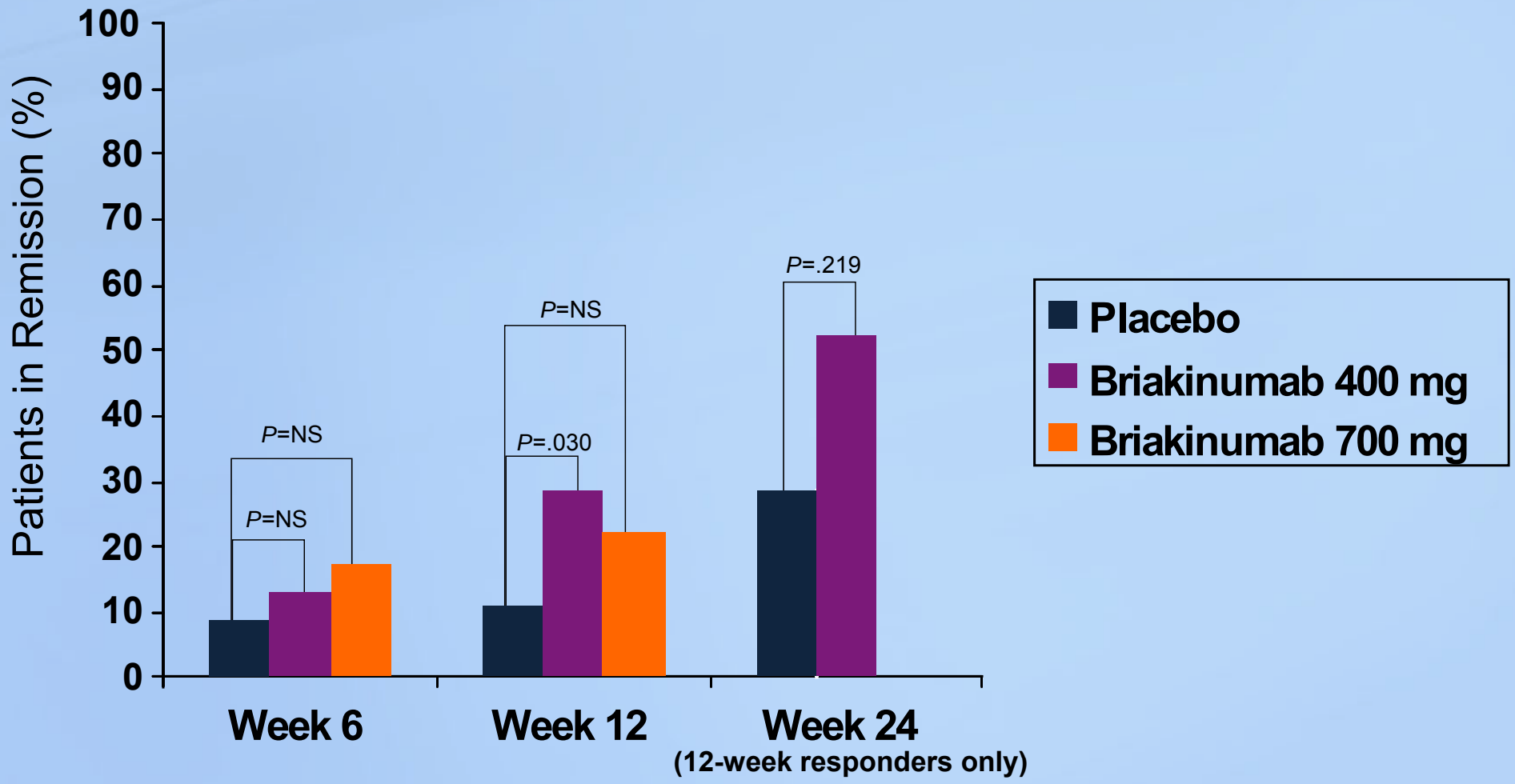
Panaccione R et al. ACG 2010

Methods

- Objective
  - Evaluate efficacy of briakinumab (anti-IL-12/23p40) for the induction and maintenance treatment of CD
- Patients (N=230)
  - Moderately to severely active CD (CDAI 220-400)
- Induction treatments (administered by infusion at weeks 0, 4, 8)
  - Briakinumab 700 mg
  - Briakinumab 400 mg
  - Placebo
- Maintenance treatment (12-week responders only)
  - Patients who responded to briakinumab 400 mg or placebo received maintenance treatment with the same therapy at weeks 12, 16, and 20
  - Patients who responded to briakinumab 700 mg were rerandomized to maintenance briakinumab 700 or 200 mg or placebo at weeks 12, 16, and 20
- Primary endpoint
  - Clinical remission at week 6

Results

Briakinumab was not effective for induction or maintenance of remission



Conclusions

- Among patients with moderate to severe CD, briakinumab was not effective for induction or maintenance of remission.