

INTERVIEW WITH AN EXPERT:

Answers to Key Questions in Inflammatory Bowel Diseases



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Speaker Introduction

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Disclosure of Conflicts of Interest

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Dr. Stephen B. Hanauer has affiliations with Abbott Laboratories; Centocor, Inc.; Elan Pharmaceuticals; Ferring Pharmaceuticals; Procter & Gamble; Prometheus Laboratories Inc.; Salix Pharmaceuticals, Inc.; Shire; and UCB Pharma (*Consultant, Clinical Research*); and Astra Zeneca; McNeil-PPC, Inc.; and Millennium Pharmaceuticals, Inc. (*Consultant*).

Today's Goals

- Identify lifestyle factors impacting quality of life including: flares, diet, stress and smoking
- Identify current and emerging treatment strategies for IBD
- Review the latest research
- Answer questions

What recommendations do you have for flare prevention and enhancing quality of life?

Understanding Triggers for Flares

- Lapses in taking medications
- Incorrect dosing of medications
- Use of nonsteroidal anti-inflammatory drugs (NSAIDS) and antibiotics
- Diet
- Stress
- Smoking

Maintaining Remissions and Preventing Flares

- What you can do:
 - Take all IBD medications as directed by your doctor
 - Always talk to your doctor before changing medications or dosages
 - Avoid anti-inflammatory medications
 - Don't smoke
 - Know *your* trigger foods
 - Eat a well-balanced diet

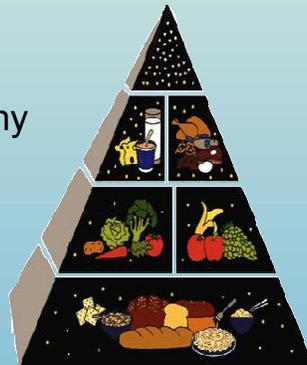
How should patients manage and maintain their nutritional sustenance?

Role of Diet and Nutrition in IBD

- Diet and nutrition are important parts of IBD management
- No evidence that diet can *cause* or *cure* IBD
- IBD is not related to food allergy but may be worsened by food intolerance
- Proper diet may
 - Improve symptoms of IBD
 - Promote healing

Diet and Nutrition Strategies to Help Control IBD Symptoms

- Create a food journal
 - Know and avoid your trigger foods
- Strive for a well-balanced, healthy diet based on:
 - Hydration
 - Adequate nutrient intake
- Consider vitamin and mineral supplementation



What role does stress play in IBD?

What We Know About Stress and IBD

- No causal link between stress and IBD
 - No personality “type” linked to IBD
- Stress can affect the digestive tract
 - Impacts IBD symptoms
- Further research is needed to determine the effectiveness of stress reduction interventions



What is the impact of smoking on IBD?

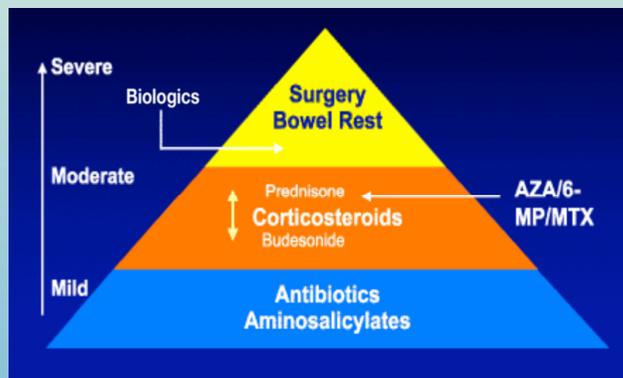
Smoking and IBD

- Smoking increases risk and worsens disease course in CD
- Smoking may reduce the risk for UC
 - Researchers are looking at the anti-inflammatory effects of carbon monoxide
- Smoking increases risk for many other diseases

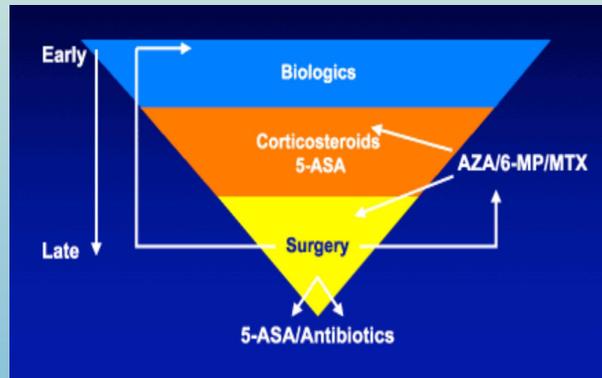
Not recommended as “treatment” for IBD

What is the difference between the “top-down” and “bottom-up” approach?

Current Standard Approach: “Bottom-Up”



Treating IBD “Top-Down”: The Future?



What are some of the long-term side effects of medication for IBD?

Long-Term Side Effects of IBD Medication

- The goal of IBD therapy is to keep patients in remission without steroids
 - Corticosteroids can have serious side effects
- Immunomodulators have a low risk of long-term side effects
 - Important to have monitoring blood tests
- Anti-tumor necrosis factor (TNF) biologics have a small increased risk of infections
- Generally no increased risk for cancer
 - Azathioprine and 6-mercaptopurine associated with a slightly increased risk of minor skin cancers

Crohn's & Colitis Foundation of America. Available at: www.cdfa.org/info/treatment/maintenance. Accessed March 18, 2009.

Preventing Complications from IBD Therapies

- Make sure your immunizations are up to date *before* starting steroids, immune suppressants or biologics
 - Including Hepatitis A & B, HPV, Pneumonia
 - Yearly influenza vaccines
- Take calcium and vitamin D supplements with steroids
 - Bone Density tests after 3-6 months on steroids
- Monitor Blood Counts every 3 months on immune suppressants
- Blood counts and chemistry evaluation yearly while on medications for IBD

What is the impact of drug therapy for IBD on pregnancy in women and fertility in men?

Key Issues in Fertility and Pregnancy

- IBD has little effect on fertility
- IBD should be controlled before pregnancy
- In some instances, IBD can actually improve during pregnancy
- In most cases, medication schedules can and should be maintained during pregnancy

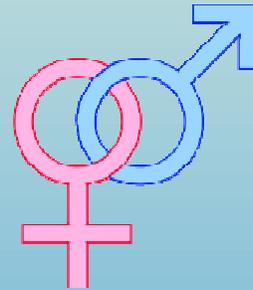
Pregnancy, Fertility, and IBD Drugs

Women

- Aminosaliclates and corticosteroids appear to be safe
- Drugs to avoid:
 - Methotrexate
 - Antibiotics
 - Thalidomide

Men

- Drugs to avoid:
 - Sulfasalazine (Azulfidine®)
 - Methotrexate
 - 6-Mercaptopurine (6-MP, Purinethol®)
 - Azathioprine (Imuran®, Azasan®)



Adis International Limited. *Drug Ther Perspect.* 2001;17:8-11.

What are your recommendations to patients considering complementary and alternative medicine (CAM) and where does the research stand on this?

Evaluating CAM Therapies for IBD

- For the most part, CAM therapies have not been proven effective in controlled clinical studies
- Some CAM therapies include:
 - Probiotics
 - Fish oil supplements
 - Green tea
- It is important to discuss CAM therapies with your doctor before beginning any treatment
- CAM should not replace prescribed therapies

**When is surgery considered the
next treatment option in
IBD patients?**

The Surgery Decision

- Elective surgery
 - Disease that is difficult to treat or manage
 - Intolerable medication side effects
 - Unresponsiveness to medical therapy
 - Persistent symptoms (fatigue, weight loss, pain)
 - Significant dietary restrictions and poor quality of life
- Emergency surgery
 - Perforations
 - Obstructions
 - Toxic megacolon

Surgery for IBD

Crohn's Disease

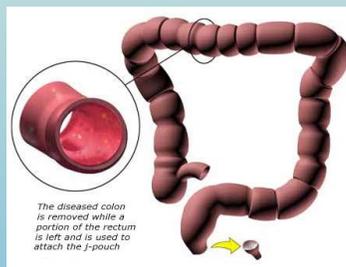
- Strictureplasty
- Resection of small intestinal segment
- Colectomy (partial or complete)
- Proctocolectomy

Unlike UC, CD cannot be cured with surgery

Ulcerative Colitis

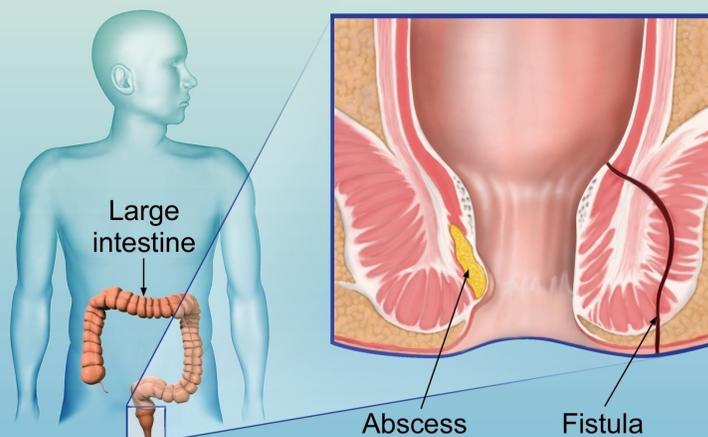
- Proctocolectomy
 - With ileostomy
 - Restorative (ileoanal or J pouch)

Disease is cured after the colon is removed



What are fistulas and abscesses and how are they treated?

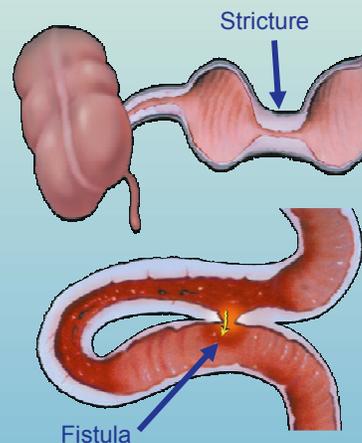
IBD Complications: Perianal Abscess and Fistula



Does the behavior of CD change over time?

Behavior of CD Over Time

- *Location* of disease *does not* tend to change over time
- *Behavior* of the disease *does* often change over time
 - Risk of complications can increase with time



Can you give us some insight into the cost of IBD?

Cost of IBD

- Both monetary and physical costs of IBD are high
- Direct costs:
 - \$1.4 million outpatient visits per year in US
 - 92,000 hospitalizations per year
 - \$534 million spent on IBD prescription medications per year

Total medical cost per year: \$1.4–\$1.8 billion
- Indirect costs are more difficult to measure
 - Include time lost from work and school
 - Total disability cost per year: \$0.4–\$0.8 billion
- Cost of IBD increases with nonadherence to treatment



How do you prevent IBD in children?

Preventing IBD

- IBD is a disease of cleanliness
 - Poor sanitation actually protects against IBD
 - Children need exposure to bacteria
- Use of antibiotics and anti-inflammatory medications should be limited



What can we expect in research in the next year?

IBD Research

- Genetics
 - Several genes linked to both CD and UC
 - Large genome-wide studies continue
- Biological markers
 - Measurable substances that may help characterize disease



IBD Research: Novel Treatments

- Over 15 new medications for IBD are currently being studied in clinical trials
- Novel therapies include:
 - Antibiotics
 - Rifaximin (Xifaxan®)
 - Hormone analogs
 - Teduglutide
 - Interferon beta-1α (Avonex®)
 - Steroids with new delivery systems
 - COLAL-PRED®
 - Extracorporeal photopheresis

National Institutes of Health. Available at: www.clinicaltrials.gov. Accessed March 31, 2009.

Questions and Answers