Complementary and Alternative Medicine in Inflammatory Bowel Disease: East Meets West

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Inflammatory Bowel Disease Clinic
Clinical Assistant Professor
The University of Calgary
Questions…. 

• How many of you have tried to use complemtary therapies either presently or in the past for your IBD?

• Yes, on them now
• No, never
• Yes, but not on them now
Questions….

• Of those of you who have used complementary therapies, what did you use?
  
  • A) acunpuncture
  • B) herbal therapies
  • C) Probiotics
  • D) Other
Questions....

• Does the level of objective evidence for a complementary therapy make any difference in your decision to use one or not (i.e. does it matter to you if it's been studied in a "Western medical" sense)?
  • Yes
  • No
How Common is the use of CAM in Patients with IBD?

- Europe > North America

- **Germany**: Sample of 413 pts with IBD (246 CD, 164 UC)  
  - 52% reported past or present use of CAM  
    - 55% homeopathy  
    - 43% probiotics  
    - 38% naturopathy  
    - Boswellia serrata extracts (36%)  
    - Acupuncture/traditional Chinese medicine (33%)

Joos et al. BMC Comp and Alt Med 2006; 6:19
How Common is the use of CAM in Patients with IBD?

- Europe > North America

**France:**
- Sample of 325 pts with IBD (219 CD, 94 UC)
- 21% reported past or present use of CAM
  - 41% homeopathy
  - 35% magnetic therapy
  - 33% acupuncture

Bensoussan *et al* Gastro Clin et Biol 2006; 30: 14-23
Why do Patients Choose to Use Alternative Therapy?

- **Calgary study:**
  - Questionnaires to 2828 members of CCFA re: CAM use
  - Logistic regression used to determine factors associated with CAM use

Why do Patients Choose to Use Alternative Therapy?

- **Both UC and CD:**
  - Severe disease
  - Use of CAM for other purposes (other than IBD)
  - Use of exercise and prayer for IBD
  - Desire for active role in treatment
- **CD only:**
  - Younger age
- **UC only:**
  - Lack of confidence in their physician

Li *et al* Can J Gastro 2005; 19(9):567-73
Why do Patients Choose to Use Alternative Therapy?

• Factors that seem to predict the use of CAM in IBD studies:
  – High steroid usage
  – Health conscious lifestyle
  – Academic education
  – Longer duration of disease
  – A Desire to feel in control
  – Fear of surgery

Langhorst et al IBD 2005; 11(3): 287-295
What Alternative Therapies are we Talking About?
What Alternative Therapies are we Talking About?

- Homeopathy
- Naturopathy
- Traditional Chinese Medicine (incl acupuncture)
- Probiotics
- Meditation/Hypnotherapy
- Herbalism
- Dietary manipulation
- Vitamins
- Chiropractic/Massage
- Bioelectromagnetic field therapy
Be a Consumer

Why does she say that? How do I know? Has it been studied? Does she benefit from giving this to me?

This medication is great. It’s safe and will make you feel better!
Therapies for which there is some “conventional” evidence

- Acupuncture/moxibustion
- Aloe vera gel
- Boswellia serrata
- Curcumin
- Wormwood
- Andrographis paniculata
- Probiotics
Acupuncture and Moxibustion

"Damp hot diarrhea"

Moxibustion: the application of heat to the acupuncture points in addition to acupuncture needles
Acupuncture and Moxibustion
Single-centre single blind randomized controlled trial

Ulcerative Colitis

29 Patients
- 18-65 yo
- >2 y hx of UC
- Mild to mod dis (CAI 4-10)
- Stable Con meds for 4wks and stable throughout trial

10 Acu/Mox sessions over 5 weeks
N=15
- No of stools
- Blood
- Well being
- Pain
- Fever
- EIM
- ESR
- Hg

10 Sham sessions over 5 weeks
N=14

1^o endpoint: change in CAI at 5 weeks

Joos et al Scand J of Gastro 2006; 41:1056-1063
Study Timeline

Baseline 5 sessions              10 session                   16 weeks f/u

CAI CAI CAI

Joos et al Scand J of Gastro 2006; 41:1056-1063
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Acupuncture group</th>
<th>Sham group*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex F/M</td>
<td>9/6</td>
<td>10/4</td>
</tr>
<tr>
<td>Age</td>
<td>39.6±13.1</td>
<td>35.8±12.0</td>
</tr>
<tr>
<td>Duration of disease</td>
<td>6.2±6.0</td>
<td>6.3±6.9</td>
</tr>
<tr>
<td>Steroids</td>
<td>47%</td>
<td>36%</td>
</tr>
<tr>
<td>5-ASA</td>
<td>73%</td>
<td>79%</td>
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<tr>
<td>Prior CAM use</td>
<td>60%</td>
<td>71%</td>
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<tr>
<td>Relaxation</td>
<td>20%</td>
<td>21%</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>Homeopathy</td>
<td>20%</td>
<td>29%</td>
</tr>
<tr>
<td>Boswellia serrata</td>
<td>33%</td>
<td>21%</td>
</tr>
</tbody>
</table>

*All NS between groups

Joos et al. Scand J of Gastro 2006; 41:1056-1063
## Acupuncture and Moxibustion
### Ulcerative Colitis

<table>
<thead>
<tr>
<th></th>
<th>Pre-Tx</th>
<th>Post-Tx</th>
<th>P-value</th>
<th>Follow up</th>
<th>P-value</th>
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<tr>
<td><strong>CAI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acup</td>
<td>8.0±3.4</td>
<td>4.2±2.4</td>
<td>0.048</td>
<td>3.7±2.5</td>
<td>0.390</td>
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<tr>
<td>Sham</td>
<td>6.5±3.2</td>
<td>4.8±3.9</td>
<td></td>
<td>4.6±3.2</td>
<td></td>
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<tr>
<td><strong>IBDQ</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Acup</td>
<td>146±23</td>
<td>182±18</td>
<td>0.065</td>
<td>168±28*</td>
<td>0.379</td>
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<tr>
<td>Sham</td>
<td>157±20</td>
<td>183±23</td>
<td></td>
<td>178±15*</td>
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<tr>
<td><strong>VAS</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Acup</td>
<td>3.0±1.8</td>
<td>1.8±1.0</td>
<td>0.980</td>
<td>2.1±1.9</td>
<td>0.913</td>
</tr>
<tr>
<td>Sham</td>
<td>3.2±1.9</td>
<td>2.2±1.7</td>
<td></td>
<td>2.9±2.1</td>
<td></td>
</tr>
</tbody>
</table>

VAS: 0=excellent, 10=poor
* p<0.05 within group **p<0.001 within group

Joos et al Scand J of Gastro 2006; 41:1056-1063
Rat Model of Ulcerative Colitis

Human colonic tissue → Healthy Rat (normal control) → Diseased Rat (model control)

Immunologic mechanism of Acupuncture?

- No treatment
  - Normal control
  - Model control
- Acupuncture

Sacrifice
- Isolate PBMC supernatant and neutrophils
  - Induction of neutrophil apoptosis by PBMC supernatant
  - PBMC supernatant levels of TNF-α, IL-1β, IL-6

**Immunologic mechanism of Acupuncture?**

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>IL-1β (pg/ml)</th>
<th>IL-6 (pg/ml)</th>
<th>TNF-α (pg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal cont.</td>
<td>8</td>
<td>44.13±22.13</td>
<td>47.05±4.28</td>
<td>119.16±33.70</td>
</tr>
<tr>
<td>Model cont.</td>
<td>8</td>
<td>280.69±111.83</td>
<td>61.32±5.48</td>
<td>172.50±35.91</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>8</td>
<td>151.38±69.86*</td>
<td>52.24±4.02*</td>
<td>129.16±24.41**</td>
</tr>
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*p<0.05 vs MC, **p<0.01 vs MC

### Immunologic mechanism of Acupuncture?

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*p<0.05 vs MC, **p<0.01 vs MC

Immunologic mechanism of Acupuncture?

Acupuncture and Moxibustion
Single-centre single blind randomized controlled trial

Crohn’s Disease

51 Patients

- 18-65 yo
- >1 y hx of CD
- Mild to mod dis CDAI 150-350
- Prednisone allowed at <15mg/d, stable for 4 wks
- Stable 5-ASA allowed
- No AZA/6-MP/MTX allowed

10 Acu/Mox sessions over 4 weeks
N=27

10 Sham sessions over 4 weeks
N=24

1st endpoint: change in CDAI

Joos et al Digestion 2004, 69(3): 131-9
Study Timeline

Baseline  5 sessions  10 sessions  12 weeks f/u  CDAI  CDAI

Joos et al Digestion 2004, 69(3): 131-9
## Baseline Characteristics

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<tr>
<th>Characteristics</th>
<th>Acupuncture group</th>
<th>Sham group*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex- F/M</td>
<td>19/8</td>
<td>17/7</td>
</tr>
<tr>
<td>Age</td>
<td>39.9±7.7</td>
<td>36.2±8.8</td>
</tr>
<tr>
<td>Duration of disease</td>
<td>10.0±5.3</td>
<td>7.9±6.0</td>
</tr>
<tr>
<td>Steroids</td>
<td>30%</td>
<td>46%</td>
</tr>
<tr>
<td>5-ASA</td>
<td>70%</td>
<td>50%</td>
</tr>
</tbody>
</table>

*All NS between groups

Joos et al Digestion 2004, 69(3): 131-9
Acupuncture and Moxibustion in Crohn’s Disease

Reduction in CDAI

Treatment phase

TCM

Control

P=0.003*

78

26

Follow-up phase

TCM

Control

P=0.088*

44

3

*ITT analysis

Acupuncture and Moxibustion in Crohn’s Disease

Comments

- Associated with a > 70 point drop in CDAI
- CDAI increased upon withdrawal of therapy
- Strong placebo effect
- Milder disease
What you should consider about acupuncture

- It’s safe…that’s a plus
- Is your acupuncturist using the same points as in these studies?
- Is it doing anything to heal your bowel ulcers? Do you care?
- The patients in these studies had milder disease
Aloe Vera Gel

- Has been used as a medicinal ingredient for over 5000 years
- Purported to have a number of biologically active compounds
- One of the most commonly used natural remedies by patients with IBD
Aloe Vera Gel
Single-centre single blind randomized controlled trial

Ulcerative Colitis

44 Patients

- 18-80 yo
- >2 y hx of UC
- Mild to mod dis (SCCAI ≥3)
- Stable Con meds for 4wks and stable throughout trial
- If on AZA/6-MP, stable for 3mo
- No topical therapy

100 ml Aloe Vera Gel BID for 4 weeks
N=30

100 ml Placebo BID for 4 weeks
N=14

1° endpoint: remission (SCCAI) at 4wks

Study Timeline

IBDQ
Baron score
SCCAI
Baseline

IBDQ
Baron score
SCCAI
4 weeks

Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Aloe Vera (N=30)</th>
<th>Placebo (N=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex- F/M</td>
<td>14/16</td>
<td>8/6</td>
</tr>
<tr>
<td>Age</td>
<td>40 (22-76)</td>
<td>36 (20-55)</td>
</tr>
<tr>
<td>Disease extent</td>
<td>6.2±6.0</td>
<td>6.3±6.9</td>
</tr>
<tr>
<td>Proctitis</td>
<td>13%</td>
<td>21%</td>
</tr>
<tr>
<td>Distal</td>
<td>27%</td>
<td>36%</td>
</tr>
<tr>
<td>Left sided</td>
<td>40%</td>
<td>21%</td>
</tr>
<tr>
<td>Pancolitis</td>
<td>20%</td>
<td>21%</td>
</tr>
<tr>
<td>5-ASA</td>
<td>70%</td>
<td>57%</td>
</tr>
<tr>
<td>Steroids</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>AZA</td>
<td>3%</td>
<td>14%</td>
</tr>
</tbody>
</table>

Aloe Vera Gel in Ulcerative Colitis

- Remission: 9/30 (Aloe vera) vs 1/14 (Placebo)  
  - P = 0.09

- Improvement: 11/30 (Aloe vera) vs 1/14 (Placebo)  
  - P = 0.06

- Response: 14/30 (Aloe vera) vs 2/14 (Placebo)  
  - P = 0.048

Aloe Vera Gel and Ulcerative Colitis

Proportion (%)

Sigmoidoscopic Score

Remission Improvement

Histologic Score

Remission Improvement

P=NS for all comparisons

Comments

- May be associated with short term improvement in symptoms
- May have improved endoscopy appearance
- Well tolerated
- *For mild disease not requiring steroids*
- Requires further study
- I do use this in my clinical practice but I always caution patients that I can’t guarantee the aloe gel they are purchasing is the same as that used in this study
Boswellia Serrata
Randomized double blind placebo controlled trial

Non-inferiority design comparing Boswellia to 5-ASA in Crohn’s Disease

83 Patients

Boswellia extract H15
N=44

Mesalamine
N=39

CDAI ↓ 90 pts with BS vs 53 with mesalamine

1⁰ endpoint: CDAI

Comments

• Boswellia appears to be “not-inferior” to a therapy which is largely considered no better than placebo

• I do not use this in my clinical practice, but it is very commonly used in Europe, especially Germany

• Available online
Wormwood for Steroid Sparing in Crohn’s Disease

Contains a number of active ingredients:

- Absinthin
- Anabsin
- Anabsinthin

Known anti-HSV, VZV, EBV, HHV, CMV properties

Induces production of interferon

*Artemisia absinthium*

1Omer et al. Phytomedicine 2007; 14:87-95
Wormwood for Steroid Sparing in Crohn’s Disease

Multi-centre double blind randomized placebo controlled trial

40 Patients

- 18-80 y
- CDAI > 170
- Stable 5-ASA for 4 weeks
- On prednisone 40mg or less for 3 weeks
- Stable AZA/6-MP/MTX allowed
- Infliximab treated pts excluded

Wormwood capsules 500mg TID

N=20

Placebo capsules 500mg TID

N=20

1st endpoint: steroid dose, CDAI at 10 weeks and after follow up

Omer et al Phytomedicine 2007; 14: 87-95
Study Timeline

Baseline

CDAI
Steroid dose
VA scale

Wormwood Placebo
Wormwood d/c
Post-treatment observation

10
Steroids resumed prn
Omer et al Phytomedicine 2007; 14: 87-95

Per-protocol steroid taper
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Wormwood</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex- F/M</td>
<td>8/12</td>
<td>9/11</td>
</tr>
<tr>
<td>Age</td>
<td>46 (21-75)</td>
<td>41 (22-67)</td>
</tr>
<tr>
<td>Duration of disease</td>
<td>6.1 (3.9-14.2)</td>
<td>4.5 (2.7-11.2)</td>
</tr>
<tr>
<td>Steroids &lt;20mg</td>
<td>40%</td>
<td>30%</td>
</tr>
<tr>
<td>Steroids &gt;20mg</td>
<td>60%</td>
<td>70%</td>
</tr>
<tr>
<td>Median CDAI</td>
<td>298 (240-321)</td>
<td>277 (238-317)</td>
</tr>
<tr>
<td>Median IBDQ</td>
<td>121 (110-152)</td>
<td>125 (123-147)</td>
</tr>
<tr>
<td>5-ASA</td>
<td>80%</td>
<td>90%</td>
</tr>
<tr>
<td>AZA</td>
<td>40%</td>
<td>30%</td>
</tr>
<tr>
<td>MTX</td>
<td>20%</td>
<td>10%</td>
</tr>
</tbody>
</table>

Omer *et al* Phytomedicine 2007; 14: 87-95
Clinical Response to Wormwood

(n=20)

CDAI

Placebo Wormwood

Week -2                          2                        6                          10                               16                         20

Tapering of steroids
Resume steroids in exacerbation
Baseline
Double blind treatment
Follow up observation period

P=0.01*

proportion with 70 pt dec. in CDAI

Omer et al Phytomedicine 2007; 14: 87-95
Steroid Sparing Effect of Wormwood

**Graph:**
- X-axis: Corticosteroid dose (mg)
- Y-axis: Corticosteroid dose (mg)
- Two lines: Placebo (red) and Wormwood (yellow)

**Legend:**
- Placebo
- Wormwood

**Table:**

<table>
<thead>
<tr>
<th>Time</th>
<th>Placebo</th>
<th>Wormwood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Double blind treatment period</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>Follow up observation period</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Tapering of Steroids</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Steroids prn on exacerbation</td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>
Quality of Life and Wormwood

IBDQ

-2 0 2 4 6 8 10 12 14 16 20

Placebo  Wormwood

Baseline | Double blind treatment period | Follow up observation period
Tapering of Steroids | Steroids prn on exacerbation
Comments

- Lack of statistical comparisons
- Mechanism of action unclear
- Prolonged steroid sparing after cessation
- Improvement in CDAI and IBDQ
- ?Something there
- Needs and warrants further study
Curcumin in Ulcerative Colitis

• Curcumin is the yellow pigment in turmeric

• Wide body of literature
  
  – 1107 articles in medline with curcumin in the title
Curcumin as an anti-inflammatory

Potent inhibition of NF-KB

Singh et al J Biol Chem 1995; 270: 24995-25000
Curcumin as an anti-inflammatory

Ameliorates TNBS colitis in mice

Sugimoto et al. Gastro 2002; 123: 1912-1922
Curcumin in Ulcerative Colitis

- December 2006
- A large study of curcumin as a maintenance therapy in ulcerative colitis
- Patients with Ulcerative colitis that were already in remission were enrolled to see if curcumin could help prevent relapse

Curcumin Maintenance Study in Ulcerative Colitis
Multi-centre double blind randomized controlled trial

89 Patients

- 13-65 yo
- Quiescent disease (CAI ≤4)
- On no steroids at baseline
- No AZA/6-MP/CSA allowed

Curcumin 1g po BID + 5-ASA
N=45

Placebo 1g po BID + 5-ASA
N=44

1° endpoint: CAI and EI at 6 mo and post-follow up

5-ASA = 1.0-3.0g/d SZ or 1.5-3.0g/d mesalamine
Hanai et al Clin Gastro Hep 2006; 4:1502-1506
Study Timeline

Baseline

<table>
<thead>
<tr>
<th>CAI</th>
<th>CAI</th>
<th>CAI</th>
<th>CAI</th>
<th>CAI</th>
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</thead>
<tbody>
<tr>
<td>EI</td>
<td>EI</td>
<td>EI</td>
<td>EI</td>
<td>EI</td>
</tr>
</tbody>
</table>

2  4  6  12

Curcumin + 5-ASA
Placebo + 5-ASA

5-ASA alone

Post-treatment observation

Hanai et al Clin Gastro Hep 2006; 4:1502-1506
Curcumin in Ulcerative Colitis

Hanai et al Clin Gastro Hep 2006; 4: 1502-1506

Relapse = CAI ≥5
Curcumin in Ulcerative Colitis

Proportion with recurrence (%)

Treatment phase

Follow up phase

P=0.049

P=0.43

Curcumin
Placebo

Hanai et al Clin Gastro Hep 2006; 4: 1502-1506
Curcumin in Ulcerative Colitis

<table>
<thead>
<tr>
<th></th>
<th>Curcumin</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Entry 6 months</td>
<td>Entry 6 months</td>
</tr>
<tr>
<td>CAI</td>
<td>1.3 ± 1.1</td>
<td>1.0 ± 2.0</td>
</tr>
<tr>
<td></td>
<td>1.0 ± 1.1</td>
<td>2.2 ± 2.3</td>
</tr>
<tr>
<td>P value</td>
<td>0.038</td>
<td>0.0003</td>
</tr>
<tr>
<td>EI</td>
<td>1.3 ± 0.8</td>
<td>1.3 ± 1.0</td>
</tr>
<tr>
<td></td>
<td>0.8 ± 0.6</td>
<td>1.6 ± 1.6</td>
</tr>
<tr>
<td>P value</td>
<td>0.0001</td>
<td>0.0728</td>
</tr>
</tbody>
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CAI: colitis activity index  EI: endoscopic index  
Hanai *et al* Clin Gastro Hep 2006; 4: 1502-1506
### Curcumin in Ulcerative Colitis

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<tr>
<td></td>
<td>Entry</td>
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</tr>
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</tbody>
</table>

Hanai et al/ Clin Gastro Hep 2006; 4: 1502-1506
Comments

- Milder disease (AZA/6-MP/steroids excluded)
- Maintenance of remission, not induction for active disease
- ?Synergy with 5-ASA

- Definitely something there
Food for thought

Pre-Infliximab

Post-Infliximab

Pre-Curcumin

Post-Curcumin
Andrographis Paniculata

• First botanical to be evaluated under new FDA regulations evaluating herbal therapy for clinical trials
• Known to inhibit NF-KB, TNF, IL-6
HMPL-004 for Active Mild to Moderate UC

Efficacy endpoints for induction (week 8)

- Mayo response
- Mayo Remission
- Mucosal healing

All p < 0.05 vs. PBO

- PBO (n=75)
- HMPL-004 1800 mg/d (n=74)
- All HMPL-004 (n=144)

- Good overall safety profile

Andrographis Paniculata Extract

A Word on Probiotics

- Crohn’s Disease: Largely have been shown to be ineffective in randomized controlled trials.
- Ulcerative Colitis: Reasonable evidence for E. Coli Nissle (Mutaflor) and VSL#3 for mild to moderate UC.
The Dark Side of Complementary Medicine

- A drug is a drug is a drug……

- Lack of standardization

- Contamination (mercury, arsenic, lead, human placenta)

- Lacing with prescriptions drugs (eg. Corticosteroids)

- Fatal liver and kidney failure have been reported after ingestion of various traditional Chinese herbal preparations

Joos et al Digestion 2004, 69(3): 131-9
Beware of Unrealistic Claims

• “Most of our clients use AloeElite for moderate to severe Crohn's. When used as directed, we have a 97% to 98% success rate” Aloeelite website
Some Final Thoughts

• Be a consumer…both with conventional therapy and with CAM
• Communicate with your doctor about your use of CAM
• We need to be open minded
• You need to be smart
• We need to study these therapies more