Complementary and Alternative Medicine: Benefits, Role, and Risks for Bone Marrow Failure Disease Patients

Overview
- Define complementary and alternative medicine (CAM)
- Provide preliminary evidence for its role in symptom management for bone marrow failure diseases
- Present patient reported data on massage and yoga
- Practice a mind-body therapy

CAM
- **Complementary** medicine is used with conventional medicine.
  - Example: Gentle yoga for strength and flexibility during treatment
- **Alternative** medicine is used in place of conventional medicine.
  - Example: Dietary supplement instead of undergoing conventional treatment

National Center for Complementary and Alternative Medicine: www.nccam.nih.gov
Recognition of the Field

- 1993 National Institute of Health creates Office of Alternative Medicine
- 1998 name changed to National Center for Complementary and Alternative Medicine

Integrative Medicine

- Integrates complementary therapies with evidence of safety and effectiveness into conventional medical treatment with goals of:
  - optimizing health promotion
  - preventing disease
  - improving patient outcomes
  - managing symptoms
  - improving quality of life

Types of CAM

- **Natural Products:** botanicals (herbs), animal-derived extracts, vitamins, minerals, fatty acids, amino acids, proteins, prebiotics and probiotics, whole diets, functional foods

- **Manipulative and Body Based Practices:** spinal manipulation, massage therapy
Types of CAM

- **Mind and Body Medicine**: range of techniques focusing on the interaction between the brain/mind, body, and behavior
  - Yoga, Qi gong, Tai Chi
  - Acupuncture
  - May also be classified into other CAM categories
  - Meditation
  - Relaxation techniques
  - Also part of psychological counseling, which is a conventional mind-body therapy

Types of CAM

- **Other Therapies**: broad range of techniques
  - Movement based (Pilates),
  - Energy based (Reiki, healing touch)
  - Whole medical systems (Traditional Chinese Medicine, homeopathy)

CAM Use in the U.S.

- National Health Interview Survey (2008)
- Some differences in use based on race/ethnicity, age

Research Evidence/Practice Guidelines

- CAM use in bone marrow failure disease not documented
- Some evidence for use in oncology and bone marrow transplant patients
  - Practice guidelines developed in 2009

1A: strong recommendation, high quality evidence
1B: strong recommendation, moderate-quality evidence
1C: strong recommendation, low/very low quality evidence
2A: Weak recommendation, high quality evidence
2B: Weak recommendation, moderate quality evidence
2C: Weak recommendation, low/very low quality evidence


DIETARY SUPPLEMENTS

Help or Harm?

A Short History of Medicine:
"Doctor, I have an earache."

- 2000 BC  "Here, eat this root."
- 1000 AD   "That root is healing. Say this prayer."
- 1850 AD   "That prayer is superstitious. Drink this potion."
- 1900 AD   "That potion is ineffective. Swallow this pill."
- 1950 AD   "That pill is ineffective. Take this antibiotic."
2,000 A.D.

“That antibiotic doesn’t work anymore. Here, eat this root.”

**History of Herbology**

- 2000 BC King of Sumeria ordered a book of herbal remedies
  - 250 substances including garlic
- 1st Century AD Greeks & Romans listed 950 medicinal products
  - 600 from plants

**1900’s**

- Scientific advancements
- Technology
1906 Food and Drug Act

- Created due to snake oil sales, etc
- Addressed misleading labeling
- Not safety or efficacy

Dietary Supplement De-regulation:

- 1994 Dietary Supplement and Health Education Act (DSHEA)
  - Don’t have to be proven safe
  - Don’t have to be proven effective
  - May not be removed from market unless proven unsafe

- If FDA has concerns about a particular dietary supplement product or ingredient, the agency bears the burden of proof to require removal of the product from
  - No processing, harvesting, packaging standards

Dietary supplement Label Regulated by the Federal Trade Commission (FTC)

Health Claims Cannot:
- Claim that a product prevents, cures or treats a condition or disease

Health claims can:
- Describe link between nutrient and deficiency disease

Examples:
- “Calcium builds strong bones”
- “Antioxidants maintain cell integrity”
- “Fiber maintains bowel regularity”

Disclaimer: This statement has not been evaluated by the Food and Drug administration. This product is not intended to diagnose, cure, or prevent any disease
The “Natural” Mystique

- Natural ≠ Safe
- Natural ≠ Effective
- Natural ≠ Good

30% of all modern drugs have come from plants and trees (ex. Digoxin, Taxol)

Toxic “Natural” products include hemlock, arsenic, and poisonous mushrooms

The Folate Paradox

It’s in the Timing

- Early phases of the cancer process, abundant amounts seemed to protect animals but once a precancerous group of cells existed, it actually served as fertilizer
- “Giving folic acid to cancer cells is like putting oil on the fire. The effects of folic acid also appear to be gene specific, where the same manipulation in one gene can give the opposite effect in another.”
  - Young-In Kim, MD, an Associate Professor in Nutritional Sciences at the University of Toronto

The Folate Paradox

A Dual Effect

- Folic acid -- the synthetic form of folate, a B vitamin found naturally in many foods
  - green leafy vegetables
  - whole grains and legumes
- In the 1940s, folic acid was given to children with leukemia.
  - their cancer worsened
  - led to a folate-blocking chemotherapy still used today
**Dietary Supplements Help or Harm?**

- Chronic Zinc supplementation can lead to copper deficiency resulting in bone marrow failure
  - *Haematologica* 2008; 93:e1-e5
  - Hypocupremia and bone marrow failure

**Is It Really FDA Approved?**

- FDA approves new drugs
- FDA does not approve companies
- FDA does not approve medical foods
- FDA does not approve the food label, including Nutrition Facts
- FDA does not approve dietary supplements
- FDA does not approve structure-function claims on dietary supplements and other foods

**Calcium Deficiency**

- At risk populations
  - Children and youth
  - Post-menopausal women
  - Elderly
  - People with poor diets, lacking in dairy foods
Integrative Nutritional Plan

- Utilize food as a source of health and energy
- Emphasis on food first
- Supplements are supplements to food
- Supplements are used to fill in where diet cannot cover everything.
- Mediterranean/Anti-inflammatory diet

Vitamins and Minerals

- Iron, vitamin C and B vitamins for making blood cells
- Antioxidants to help maintain integrity of cells
- Electrolytes: Sodium, potassium, phosphorus
- Calcium and vitamin D for bone health
**Vitamin D Functions**

- Many uses in the body
  - Promotes absorption of calcium from the small intestine
  - Maintain blood levels of calcium and phosphate for bone formation, mineralization, growth, and repair
  - Improves muscle strength and immune function
  - Reduces inflammation

**Vitamin D Deficiency**

- At risk populations
  - Breastfed infants
  - Older adults
  - People with limited sun exposure
  - Darker skin pigments
  - Certain religious groups

**Food Sources of Vitamin D and Omega-3**

- 3 oz smoked salmon = 583 IU
- 3 oz light tuna, canned in oil = 229 IU
- 1 large, whole egg = 29 IU
Mushrooms

- While white button mushrooms start out as a good source of vitamin D, if they are exposed to UV for as little as 5 minutes after harvesting, they provide up to 869% of the daily value of vitamin D.


Calcium Content of Foods

- 8 oz milk = 300 mg
- 8 oz low-fat yogurt = 230 mg
- ½ cup cooked Spinach = 120 mg
- 1 cup Cheerios = 100 mg

Dietary Supplements

- Calcium
  - Carbonate or citrate
  - Dose dependent absorption
  - Two doses per day
- Vitamin D
  - D2 or D3
  - D3 is best
Some Evidence of Help without Harm

- Ginger or ginger tea for nausea
- Omega-3 fatty acids (DHA/EPA) – no more than 2 gms per day
- Mushrooms
- Green tea (unless taking Velcade)
- Cruciferous vegetables (indole 3-carbinols)
- Garlic
- Chromium

http://ods.nih.gov

Dietary Supplements, Vitamins, and Herbs Voluntary Testing
Acute Selenium Toxicity from Dietary Supplement

- 201 cases of adverse events associated with liquid selenium product
- Found to contain 200 times the amount on label
- Median dose 41,749 microg/day as compared to recommended dose of 55 microg/day
- Toxicities: fatigue, hair loss, joint pain, nausea

Archives of Internal Medicine 2010 Feb 8;170(3)

www.consumerlab.com

www.nccam.nih.gov
**Summary:**

**Dietary Supplements, Vitamins, and Herbs**

- Natural does not mean safe
- Can interact with medications
- Herbs and high dose vitamins can be toxic
- Not regulated by government
- Not approved by FDA
- No requirements for pre-market testing for safety or effectiveness

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**Research Evidence: Manipulative and Body Based Practices**

<table>
<thead>
<tr>
<th>Massage</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>✓ Pain (guideline 1C)</td>
</tr>
<tr>
<td></td>
<td>✓ Nausea</td>
</tr>
<tr>
<td></td>
<td>x Vomiting</td>
</tr>
<tr>
<td></td>
<td>✓ Fatigue</td>
</tr>
<tr>
<td></td>
<td>✓ General distress</td>
</tr>
<tr>
<td></td>
<td>✓ Anxiety (guideline 2C)</td>
</tr>
<tr>
<td></td>
<td>x Sleep</td>
</tr>
<tr>
<td></td>
<td>? Vasovagal Sxs (not ranked)</td>
</tr>
</tbody>
</table>
Risks of Massage

- Bleeding/bruising (low platelet levels, blood thinners)
- Blood clots (DVT)
- Lowered immunity (white cell counts)
- Increased pain or infection in individuals with open wounds, dermatitis, cellulitis
- Medical devices (for ex: uretal stent displacement)
- Sensory changes (for ex: neuropathy)
- At risk for potential for fractures
- Training of provider (for ex: lack of medical or oncology certification)


Research Evidence: Mind and Body Medicine

<table>
<thead>
<tr>
<th>Acupuncture</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion of slim needles</td>
<td>√ Pain (guideline 1A)</td>
</tr>
<tr>
<td>Can include electrical</td>
<td>√ Nausea – chemo (1A)</td>
</tr>
<tr>
<td>stimulation</td>
<td>√ Vomiting – chemo (1A)</td>
</tr>
<tr>
<td>Acupressure = no needles</td>
<td>? Fatigue (post chemo) (2C)</td>
</tr>
<tr>
<td></td>
<td>x General distress</td>
</tr>
<tr>
<td></td>
<td>x Anxiety</td>
</tr>
<tr>
<td></td>
<td>? Sleep</td>
</tr>
<tr>
<td></td>
<td>x Vasovagal Sxs (fat Kaluc)(1B)</td>
</tr>
</tbody>
</table>


Risks for Acupuncture

- Not advised when risk of bleeding and infection is high
  - patients with neutropenia, thrombocytopenia
- Not advised when
  - at risk for endocarditis due to heart valve abnormality
  - pregnant (select points)
  - affected limb of patients with lymphedema
  - electrical stimulation of patients with pacemakers or electronic medical devices
- Untrained practitioners
  - Studies of trained practitioners in Europe and Japan show < 0.2% of individuals experience adverse effects
  - Most commonly reported: failure to remove needles, bleeding, bruising, dizziness, and pain

Cassileth, BR et. al, PDQ Integrative Oncology Complementary Therapies in Cancer Care. 2005, Hamilton: BC Decker
**Research Evidence: Mind and Body Medicine**

**Meditation**

- Focus on one point of attention (mantras, breath) or emotional state
  - Mindfulness = “non-reactive, non-judgmental moment to moment awareness” of one’s experience
- Benefits:
  - √ Pain
  - √ Nausea
  - x Vomiting
  - x Fatigue
  - √ General distress (guideline 1B)
  - √ Anxiety (guideline 1B)
  - x Sleep
  - ? Vasovagal Sxs (not ranked)

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**Yoga**

- Combines physical movement, breath control, and meditation
- Benefits:
  - √ Pain (guideline 1B)
  - √ Nausea
  - x Vomiting
  - √ Fatigue
  - √ General distress (1B)
  - √ Anxiety (1B)
  - √ Sleep
  - ? Vasovagal Sxs (not ranked)

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**Relaxation/Guided Imagery**

- To establish a state of deep relaxation or distraction
- Techniques include deep breathing, active or passive muscle relaxation, visualization
- Benefits:
  - √ Pain (1B)
  - √ Nausea
  - √ Vomiting
  - x Fatigue
  - √ General distress (1B)
  - √ Anxiety (1B)
  - √ Sleep
  - ? Vasovagal Sxs (not ranked)
Conclusions

- CAM recommended as part of multi-modal treatment of symptoms
- Don’t assume natural products are safe
- Acupuncture not recommended for patients with risk of bleeding or infection; check with your doctor
- Massage from a certified provider, gentle Yoga, Meditation, and Relaxation are generally safe and may lead to improvements in quality of life

Integrative Medicine Program Data

Massage: Outpatient
Number of Ratings = 639

Integrative Medicine Program Data

Massage: BMT Patients
Number of Ratings = 1,345

Reductions
- Pain: 36%
- Nausea: 30%
- Fatigue: 35%
- Anxiety: 40%
- Physical: 42%
- Emotional: 40%
- QOL: 31%
**Integrative Medicine Program Data**

**Yoga: Outpatient**
Number of Ratings = 1750

**Integrative Medicine Program Data**

**Meditation Outpatient**
Number of Ratings = 94

**Additional Resources**
- Dr. Herbert Benson’s website
  - [www.relaxationresponse.org](http://www.relaxationresponse.org)
- National Center for Complementary and Alternative Medicine
- Center for Mindfulness in Medicine, Health Care, and Society
  - [www.umassmed.edu/cfm/home](http://www.umassmed.edu/cfm/home)
Moffitt Cancer Center
Integrative Medicine Program
Email: wellness@moffitt.org
Website: www.insidemoffitt.com/integrative-medicine.htm
Phone: 813-745-6052