

# Botanicals Supplements – Integrative Medicine in Primary Care



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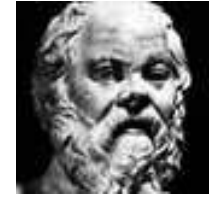
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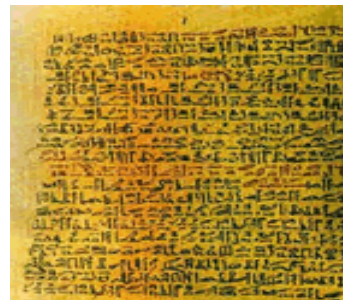
# Lecture Components

1. History and Philosophy of Botanicals
2. Five common Botanicals – uses, mechanisms of action, side effects, interactions, contraindications and clinically tested products
3. Research evidence of efficacy

# 1. History and Philosophy



- 'Phytomedicine'/Botanical Medicine has been used for thousands of years and is one of the oldest methods of healing
- Ebers Papyrus (Egypt 1550BC)- described over 700 herbal/mineral/animal based remedies (Senna, Opium, Cannabis, Garlic)



# History and Philosophy cont'd

- Hippocrates (Greece 460-777BC)  
“Father of Modern Medicine” – the Corpus (>60 works) contains 400 herbal remedies
- First line → fresh air, healthy food, pure water and rest!



# History and Philosophy cont'd





# History and Philosophy cont'd

- In 1985 W.H.O. estimated that 80% of World Population used Botanical Medicine as a Primary Care resource
- Many modern drugs are derived from plants – Digitalis, Atropine, Cromolyn, ASA
- Eisenberg et al 1998 JAMA- herbs was second most commonest CAM modality used in US
- CDC 2005 19% population taking supplements (not vitamins/minerals)
- *British Journal of General Practice* 2004,(54), 439-441 “92% of patients not disclose to GP” about botanicals they are taking.



# History and Philosophy Cont'd

- Botanical Medicine includes – European, Chinese, Ayurvedic, Native American and other traditions
- Herbal Extracts: **Water**- hot infusion (tea), cold infusion (macerate), decoction (soup), steams, **Hydroethanolic** – tinctures (1:5, 1:10), fluid extracts (1:1)- via percolation or maceration, **Glycerite/Oil**
- Methods of Application: oral, transdermal (poultice, compress), PV, inhalation, etc



# Top-7-leading Uses for Botanicals Remedies

1. Colds
2. Burns
3. Headaches
4. Allergies
5. Rashes
6. Insomnia
7. PMS





# Top-9-selling Herbs in 2005

<b>Name of Herb</b>	<b>Rank</b>
Garlic	1
Echinacea	2
Saw Palmetto	3
Ginkgo	4
Cranberry	5
Soy	6
Ginseng	7
Black Cohosh	8
<i>Source:</i>	<b>American Botanical Council</b>

# Five common Botanicals



# Cimicifuga/Actae Racemosa – Black Cohosh

- Used for centuries by Native Americans for rheumatism and labor
- WHO and Commission E  
1) Menopausal Symptoms 2) PMS 3) Dysmenhorrea
- Unclear: E-Receptor?
- S.E. Mild GI probs
- Interactions – Tamoxifen (AAFP)
- Contra – Pregs b'cos stimulates uterine contractions/Liver Dz (warning in UK/>100 cases)
- 20-80mg B.I.D. Remifemin (alcohol) or Menofemin (isopropanolic)
- No endo stim (52 wks), no effect on breast tissue (6m)



# Echinacea Species (Purpurea, Angustifolia, Pallida)

- Native to U.S.
- URTi and LRTi – snake bite (anti-hyaluronidase)
- Non-specific immune modulation and bacteri/viricidal- Th cells
- S.E. Allergy if allergic to Daisy, Sunflower, etc
- Interactions - ?cyclosporine? Kids-Liver?
- CAVE ATOPY ( Lupus, CTD, MS- iv 1960s)
- 1-3gms (6gms) Q24- take often (dry root vs 1:5 tincture)



# Ginkgo Bilboa - Ginkgo

- One of the oldest living species of Chinese tree
- Dementia/prevention, PVD
- Active ingredients – 40+ including Ginkgolide B( anti-PAF)- antioxidant
- Increases cerebral blood flow via NO
- S.E. Vasodilation  
Headache, GI probs, Rashes, reduce BP and fsg





## Gingko Cont'd

- 240mg Q24 (24% ginkoflavones, 6% terpenes)
- Nature's Way, Purple Top
- Interactions- ANTICOAGULANTS: 15 case reports of bleeding (13 other factors also) vs 500 million doses sold in USA
- *Clinical & Lab. Hematology* 2003, 25, p213-251  
RBCPT 32 young male volunteers given Ginkgo (240mg and 480mg X2 weeks) no change on PLTs function, PT or PTT

# Panax Ginseng - Ginseng

- Adaptogen for 3000 years – Commission E and WHO “Physical and Mental Exhaustion”
- Panax Ginseng (red (steamed) vs white (crude), Panax Quinquefolius, Eleuthero
- Binds to Nicotinic Ach-R in CNS (smoking cessation), and also antioxidant, anti-platelet effect, anti-arrhythmic, lowers blood glucose
- Yang tonic-”cold and old!”





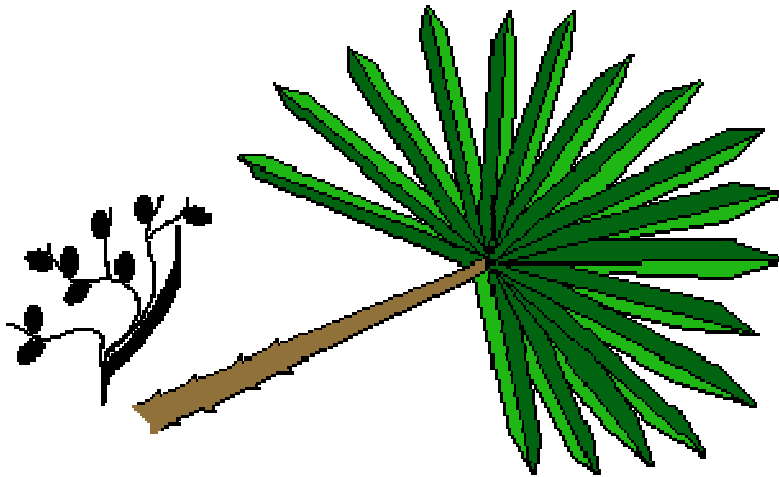
## Ginseng Cont'd

- S.E. Ginseng Abuse Syndrome – HTN, Insomnia, Hypertonia, and post-menopausal bleeding (steroid effect)
- Interactions – Stimulants, Anticoags, DM
- 100-600mg Q24 (4% Ginsenosides)
- Ginsana



# Serona Repens – Saw Palmetto

- American Dwarf Palm
- 2 million Americans
- Mild BPH as per WHO and Commission E
- NF → USP (only non drug)
- Weak 5 Reductase Inhibitor and DHT Antagonist, Anti-inflamm., Anti-Estrogen





## Saw Palmetto Cont'd

- S.E. Mild GI Probs, No ED or change in PSA
- Interactions – None (AAFP)
- 160mg B.I.D or 320mg QD – takes 8-12 weeks to work
- Permixon in Europe

### 3. Research Evidence of Efficacy



# Black Cohosh 1



- 16 Placebo controlled trials up to 2005
- Low Dog et al, *American Journal of Medicine* 2005 Vol: 118. Pages 98-108
- **Modest** effect on menopausal symptoms (hot flashes, night sweats, anxiety, insomnia)



## Black Cohosh 2

- HALT Study – Newton et al, “*Annals of Internal Medicine*”, Vol:145, Issue:12, Pages: 869-879
- 12 months (longest study), 351 women, perimenopausal aged 45-55
- 5 treatment arms; Black Cohosh, Blend, Blend + Soy, HRT, Placebo
- Rate of vasomotor symptoms (# hot flash/night sweats) and Wiklund Vasomotor Symptom Scale (intensity) 13/mild-severe

**Annals of Internal Medicine**



## Black Cohosh 3

- BC: 160mg of Ethanolic Extract (all other studies use isopropanolic extract)
- 73 women randomized to this arm
- No different from placebo @3,6,12 months
- No acute adverse effects cf placebo
- 4 studies underway including U.Penn, Columbia U.

# Echinacea 1

- Cochrane Review of 16 RCTs, Melchard et al, 2000, *Cochrane Database Systematic Review*
- 3396 participants
- Some preparations (fresh pressed juice/aerial part) **superior** to placebo



# Echinacea

- Turner et al, *New England Journal of Medicine* 2005, Vol:353 Pages 341-348
- Echinacea Angustifolia – 3 extracts (CO<sub>2</sub>, 605 Alcohol, 20% Alcohol)
- 399 University of Virginia students **900mg** extracts Q24 for 7 days or placebo before challenge
- 5 days sequestering for “Viral Challenge” with Rhinovirus 39 (everybody seronegative at outset)
- No significant difference cf placebo: rate of infection, severity of infection, volume of nasal secretions, inflammation (PMNs/IL-8) or viral titers
- WHO/Commission E 1-3gms, Herbalists 3-6gms!





# Echinacea- new study!

- Annals of Internal Medicine December 21<sup>st</sup> 2010
- RCT
- 719 patients, average age 34, 10gms day 1 → 5 gms day 2-5
- 4 groups 1) nothing 2) placebo 3) Echinacea (blinded) 4) Echinacea (un-blinded)
- Wisconsin Upper Respiratory Symptoms Survey
- Mean global **severity** 1) 286 2) 264 3) 236 4) 258
- Comparing 2) and 3) showed 28 point trend to Echinacea- did not reach statistical significance
- **Duration** 1) 7.03 2) 6.87 3) 6.34 4) 6.76- not significant



# Ginkgo Biloba

- *JAMA* Vol.300, No.19, November 19, 2008, p2253-2262 “GB for prevention of dementia”, DeKosky et al
- RDBPCT 5 academic centers between 2000-2008 (median f/u 6.1 years) 3069 aged >75 (normal 2587) (MCI 482)- assessed Q6 for dementia (neuro-psych tests)
- 120mg Q12 vs placebo
- GB group 277/1545 dementia vs 246/1524
- Dementia rate 3.3/100 person years GB vs 2.9 + GB no effect if MCI



## Ginkgo Biloba Cont'd

- *International Journal of Clinical Pharmacology and Therapeutics*, 2004, Vol 42, P63-72: meta-analysis of 9 RDBPCTs showed significant difference in favor of Ginkgo in PVD



# Panax Ginseng

- *International Journal of Clinical Pharmacological Research*, 1999 Vol 19 P89-99
- “No relief in menopause”, but did show ‘improved wellbeing’”



# Saw Palm

- Best et al, *New England Journal of Medicine*, 2006, Vol. 354 P557-566
- RDBPCT 225 men aged >49 (112 SP vs 113 Placebo) with mod-severe BPH - AUASI (American Urological Association Symptom Index 7 questions 0-7 mild, 8-19 mod. 20-35 severe) score of 15 + flow rate
- 1 year of Saw Palmetto 160mg Q24
- AUASI score: improvement SP 0.68 vs Placebo 0.72
- Flow Rate: improvement SP 0.42 vs Placebo 0.01
- No significant difference from placebo
- No SE



## Saw Palmetto- new study!

- Barry et al *JAMA* 2011; 306 (12): 1344-1351
- DBPCT in 11 sites
- > 45 years old, AUASI score 8-24 (AUASI score of < 7 is MILD)
- 320mg (1-24wks)→ 640mg (24- 48wks)→ 960mg (48-72 weeks vs placebo)
- Baseline to end AUASI score 14.4→ 12.2 in SP vs 14.69→ 11.7 with placebo
- Increasing dose of SP did not reduce LUTS symptoms cf placebo



# Practical considerations of prescribing Botanicals

- Drug-herb and herb-herb interactions
- Baseline LFTS
- Clearly state in note that risks and benefits and alternative discussed
- Use clinically tested products only-pharmaceutical grade from Europe
- E/M: as part of standard office visit

THANK-YOU

