Top 10: EBM Updates From The Medical Literature

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Probiotics Prevents Diarrhea in Preschool Children

• RXT of Healthy children 6 to 36 months attending day care
• Lactobacillus reuteri vs. placebo once/day x 3 months with F/U at 6 months

• Outcomes: While on the probiotic, ↓ in diarrhea (NNT=6.25); 6 months NNT = 2

• Mean duration of diarrhea ↓ 2.5 days to 1.4 days in first 3 months. In the second three months from 2.4 days to 1.6 days. All statistically significant.

• Also Statistically Significant:
  • ↓ URI in intervention group in first 3 months (NNT = 8.8) & in second 6 months (NNT = 2.5)
  • ↓ in days pre-school missed & a ↓ of 50% of days parents missed of work.
  • ↓ risk of antibiotic use
  • There were no adverse events.

Pediatrics. 2014: 133(4); e904-e909.
Primary Prevention of Obesity

- Evidence based statement by Am Academy of Pediatrics re: Obesity
- ↑Activity, ↓Concentrated Carbohydrates are the key message.

- Encourage breast feeding.
- Replace cookie jar with fruit bowl.

- Limit screen time to < 2 hours/day in children over age 2. No television in bedrooms or where the family eats.
- Children under the age of 2 should have no screen time.

- 60 minutes of moderate to vigorous activity every day.

Rapid Strep is Enough

- Systematic review/meta analysis on rapid antigen (RADT) for Group A strep in Adults & Children w/pharyngitis; 48 studies ~24,000 patients; culture-reference.

- Estimate of sensitivity of RADT = 0.86 and specificity = 0.96
- Analysis of studies of just children, sensitivity = 0.87 and specificity = 0.96

- Conclusions: RADTS for GAS high accuracy in both adults and pediatrics
- Negative RADT sensitive enough to NOT NEED throat culture.

- Use Centor scoring to guide testing

Modified Centor Criteria

- Tonsillar exudate or erythema: +1 point
- Anterior cervical adenopathy: +1 point
- Cough absent: +1 point
- Fever present: +1 point
- Age 3 to 14 years: +1 point
- Age 15 to 45 years: 0 points
- Age over 45 years: -1 points

Score
4 to 5: Treat with antibiotics
2 to 3: Perform rapid antigen test
   Antigen positive: Treat w/ antibiotics
   Antigen negative: Throat Culture
   Antigen negative: → Sympt Tx.
0 to 1: Symptomatic Treatment

Oral Morphine vs. Ibuprofen Post-fracture Pain in Children

- RCT of 134 children Age 5-17 for uncomplicated fractures in Canadian ER
- Mean age 10 with females compromising the majority.

- Ibuprofen 10mg/kg VS oral morphine 0.5mg/kg q 6 hours X first 24 hour period.
- Acetaminophen at 15mg/kg could be taken by both groups for breakthrough pain.
- Pain was assessed by Faces Pain Scale – Revised.

- **Results:** Morphine & Ibuprofen: **equally effective** in controlling fracture related pain
- No statistically significant differences in acetaminophen use for breakthrough pain.
- Morphine had greater adverse events. Most common nausea and drowsiness

- **Conclusion:** Ibuprofen is equivalent to morphine for fracture pain in children and teens

*CMAJ.* 2014; 186(18):1358-1363.
HPV Vaccine in Adolescent Females Does Not Increase STI Risk

- Retrospective review of insured females aged 12-18;
- If STI incidence varied vaccinated vs. unvaccinated females.

- Outcomes:
  - The overall incidence of STI increased with age
  - There was no statistical difference in STI infection with HPV Vaccinated population vs. unvaccinated population.

Conclusion: HPV vaccination in adolescent females is not associated with increased risk of STI.

What Does Increase The Risk of STI & Promiscuity in Teenage Population?
Teen LARC Access
↓ Pregnancy & Terminations

- 1,400 teenage girls (age 15-19) cohort study
  St. Louis, MO region between 2008-2013

- 72% chose either an IUD or an implanted (LARC) method

- Outcomes: Baseline                  Afterward                  Reduction
  Pregnancy                      158.5/1000                34/1000                  79%
  Births                         94/1000                   19.4/1000                78%
  Induced abortions              41/1000                   9.7/1000                 77%

NEJM 2014; 371:1316-23
Muscle Building Supplements (MSB) & Testicular Cancer

- Case control study of MBS on 356 new diagnoses of Testicular Germ Cell Cancer (TGCC) vs 513 controls from CT and MA
- Most common MBS Ingredients: creatine, protein, and androstenedione (weak androgen; or its “booster”)
- Risk of Testicular Germ Cell Cancers w/MBS was (OR = 1.65, 95% CI: 1.11-2.46).
- Association strongest: those who used MSB before age 25 years, used multiple types of MBS, and those who used MSB > 36 months

British Journal of Cancer. 2015; 112:1247-1250
Nasal Balloon for SOM

- RCT; 4–11 years w/OME in 1/both ears, confirmed by tympanometry
  Autoinflation 3 X daily for 1–3 months plus usual care vs usual care

- **Resolve:**
  \[
  \begin{array}{ccc}
  & \text{Autoinflation} & \text{Controls} \\
  1 \text{ month} & 47.3\% & 35.6\% & RR= 1.36, 95\% \text{ CI 0.99-1.88} \\
  3 \text{ months} & 49.6\% & 38.3\% & RR= 1.37, 95\% \text{ CI 1.03-1.83};
  \end{array}
  \]

- NNT =9

- Autoinflation → greater improvements in ear-related quality of life scores

- Compliance: 1 month: 89%; 3 months: 80%; AE: mild, infrequent & similar

- Interpretation: Autoinflation in children w/OME is effective in clearing effusions & improving symptoms and child and parent quality of life.

Sublingual Immunotherapy for Allergic Rhinitis and Asthma

• Europe used sublingual immunotherapy (SLIT) safely for years
• Systematic review of 63 RCT’s of 5,000 children and adults with allergic rhinitis and asthma.
• Evaluation included symptoms score, medication score, quality of life, and incidence of adverse events.
• SLIT good outcomes for asthma and moderate for allergic rhinitis
• Side effects: tingling or itching in mouth, No life threatening reaction

JAMA 2013; 309:1278
Screening
USPSTF Updates Guidelines on Using Medications to Prevent Breast Cancer

- “Adequate evidence" Tamoxifen & Raloxifene ↓ risk E receptor + breast cancer in high-risk, postmenopausal women” [B]

- High Risk: Family history of breast cancer or a personal history of breast biopsy
- Offer Rx if estimated 5-year risk of ≥ 3% (Efficacy: NNT=45)
- Providers should "engage in shared, informed decision-making" Rx vs risks

<table>
<thead>
<tr>
<th>VTE</th>
<th>Uterine Cancer</th>
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<tbody>
<tr>
<td>Tamoxifen</td>
<td>5-year risk of DVT/PE 1.2%</td>
</tr>
<tr>
<td>Raloxifene:</td>
<td>24 month risk of DVT/PE 2%</td>
</tr>
</tbody>
</table>

- Medications should NOT be used for low (<3%) women

Breast Cancer Risk Assessment Tool

An interactive tool to help estimate a woman's risk of developing breast cancer

The Breast Cancer Risk Assessment Tool is an interactive tool designed by scientists at the National Cancer Institute (NCI) and the National Surgical Adjuvant Breast and Bowel Project (NSABP) to estimate a woman's risk of developing invasive breast cancer. See About the Tool for more information.

The Breast Cancer Risk Assessment Tool may be updated periodically as new data or research becomes available.

Risk Tool

(Click a question number for a brief explanation, or read all explanations.)

1. Does the woman have a medical history of any breast cancer or of ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS) or has she received previous radiation therapy to the chest for treatment of Hodgkin lymphoma? Select ▼

2. Does the woman have a mutation in either the BRCA1 or BRCA2 gene, or a diagnosis of a genetic syndrome that may be associated with elevated risk of breast cancer? Select ▼

3. What is the woman's age? Select ▼

4. What was the woman's age at the time of her first menstrual period? Select ▼

5. What was the woman's age at the time of her first live birth of a child? Select ▼

6. How many of the woman's first-degree relatives - mother, sister, daughter - have had breast cancer? Select ▼

7. Has the woman ever had a breast biopsy? Select ▼

7a. How many breast biopsies (positive or negative) has the woman had? Select ▼

7b. Has the woman had at least one breast biopsy with clinical findings? Select ▼

8. What is the woman's race/ethnicity? Select ▼

9. What is the woman's sub-ethnicity? Select ▼
Limited Accuracy of Breast Biopsy Diagnosis

• Observational study of breast Bx Reading by Pathologists in US
• Review 60 breast biopsies w/ known diagnosis; Compared to Consensus Panel

• Concordance in diagnostic interpretations = 73% (95% CI: 73.4-77.0)

• Disagreement: biopsies from high breast density & among pathologists with low case volumes or who worked at non-academic settings

• Highest concordance for invasive carcinoma; Lowest for DCIS & Atypia

DCIS: How to Treat?

- Observational study 108,000+ women with DCIS from 1988-2011; Risk of Dying from Breast Cancer vs Death in General Population
- Mean age at Dx of DCIS was 53.8 years.
- Higher Mortality Risk for Dx < 35 years (7.8% vs 3.2%; \( P < .001 \)) & Blacks (7.0% vs 3.0%; 2.17-3.01]; \( P < .001 \)).
- Patients lumpectomy + radiotherapy \( \rightarrow \) ↓ risk of invasive recurrence at 10 years (2.5% vs 4.9%; \( p < .001 \)) but
- **NOT breast cancer–specific mortality or All Cause Mortality**

*JAMA Oncol.* Published online August 20, 2015.
“THE SECRET OF CHANGE IS TO FOCUS ALL OF YOUR ENERGY, NOT ON FIGHTING THE OLD, BUT ON BUILDING THE NEW.”

— SOCRATES
No More FLP

• Evaluation of National Health and Nutrition Survey and National Death Index on 16,000 middle age adults X 14 years.
• Compared fasting vs. non-fasting cohorts with similar characteristics.

• For all cause mortality, fasting vs. non-fasting LDL $\rightarrow$ similar prognostic values.
• Researchers did not evaluate effect of fasting on triglyceride measurements, but Rx to lower triglycerides medically has not been proven of benefit.

• Conclusion: Non-fasting lipid determination is effective for cardiovascular risk determination.

*Circulation.* 2014; 130:546.
Pass the Butter

- Systematic review & meta analysis of RCTs: dietary fat, cholesterol, and subsequent CAD of trials if published prior to release of 1977 dietary guidelines in US or 1983 in UK
- 1977/83 Fat Rec: < 30% of calories or < 10% of calories from saturated fat

**Outcomes:** Six RCTs included. *All with inconsistent findings and information*
- No Data to Support the Recommendations altered all cause mortality or CHD mortality

**Conclusions:**
- Data from RCTs available prior to 1983 do not support the dietary restrictions of fat as < 30% of daily intake or total saturated fat as < 10% of daily intake

*Open Heart.* 2015; 2(1):e000196.
Beyond PDE5 Inhibitors…
Coffee & Erections

- National Health and Nutrition Examination Survey (NHANES).
- ED identified by a question in computer interview with 24 hour dietary recall focusing on estimated caffeine intake.

- **Outcomes:** Men with intakes in the 3\(^{rd}\) quintile (85-170 mg/day: 2-3 cups) and 4\(^{th}\) quintile (171-303 mg/day: 3-4 cups) less likely to report ED vs men in the lowest

- 2-3 Cups OR = 0.58; 95% CI: 0.37-0.89
- 3-4 Cups: OR = 0.61; 95% CI: 0.38-0.97

- In overweight and obese men, and hypertensive men (but not with DM), >/= 2 cups of Coffee lowered ED risk

*PLOS ONE. 2015; 10(4):e0123547*
WALKING & ED

- Patients with acute “low risk” MI randomized
- Home-based walking program vs control (usual care)
- Baseline: 84% of patients reported ED at hospital discharge

Results:
- @ 30 days, ED had ↑by 9% in the control group from Baseline (p = 0.08).
- Home walking group had a ↓↓ ED by 71% from Baseline (p <0.0001).
- The 6-minute walk distance was higher in the walking group (p = 0.01)

Conclusion:
- Home-based walking program → improved functional capacity & ↓ ED after recent acute myocardial infarctions

Am J Cardiol. 2015 Mar 1;115(5):571-5
Venlafaxine vs. Low Dose E2 for Hot Flashes

- RCT of 340 peri- and post-menopausal women
- Venlafaxine (75mg) vs. estradiol (0.5mg) vs. placebo
  (Previous dose E2 for MP symptoms was 1.0mg)

<table>
<thead>
<tr>
<th></th>
<th>Vaso-motor Sx</th>
<th>Hot Flashes</th>
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<tbody>
<tr>
<td>Venlafaxine:</td>
<td>↓ by 48%</td>
<td>↓ by 1.8</td>
</tr>
<tr>
<td>Estradiol:</td>
<td>↓ by 53%</td>
<td>↓ by 2.3</td>
</tr>
<tr>
<td>Placebo:</td>
<td>↓ by 29%</td>
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*JAMA Inter Med. 2014: epub.*
Device-guided *slow-paced respiration* for menopausal hot flushes: a randomized controlled trial

- Peri or postmenopausal women with ≥ 4 hot flushes/d (Ave: 8.5 (±3.5)
- RCT of slow paced respiration (guided-breathing device) (< 10 breaths/minute) VS Playing relaxing music on similar device x 12 weeks

- **Results:** At 12 Week:

<table>
<thead>
<tr>
<th>All Hot Flashes</th>
<th>∫ 1.8 HF/D (28%) (95%: 0.9-2.6)</th>
<th>∫ 3.0 HF/D (-35%) (95%:2.1-3.8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mod-Severe HF</td>
<td>∫ 19%</td>
<td>∫ 44%</td>
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**CONCLUSION:**

- Device-guided slow-paced respiration → modest improvements in the frequency and severity of their hot flushes, but was less effective than music-listening intervention

*Obstet Gynecol.* 2015 May;125(5):1130-8
Medical Talk Shows and the Headache They Cause

- Reviewed Recommendations 40 2013 episodes of “The Doctor Oz Show” & “The Doctors”

- Outcome: Found “at least weak or better” evidence for 54% of recommendations.

- “The Doctor Oz Show” medical literature supported 46% of the recommendations, contradicted 15%, and showed no evidence for 39% (OR 54% were BASELESS)
  - There were approximately 12 recommendations per episode.
  - 39% were for dietary advice; only 17% of those described magnitude of benefit

- “The Doctors” the medical literature was found supporting 63% of the recommendations, contradicting 14%, and no evidence for 24% (38% BASELESS)
  - On average 11 recommendations were made per episode.
  - Most common “consult a healthcare provider” (18%) 11% Magnitude of benefit

- Conclusions: ~ 50% recommendations on medical talk shows have weak or no evidence

*BMJ*. 2014; 349:g7346.
Med Errors at Discharge

• Analysis of 470 patients (x=59 Yrs) Phone F/U 2 days after hospital discharge for ACS or heart failure; average discharge medications = 12 meds.

• In 51% of the patients, researchers found at least 1 discordant medication. Discordant—appeared on discharge list or patient-reported list but not both.
• 27% of patients were not taking at least 1 prescribed medication.
• 36% were taking at least 1 non-prescribed medication.
• 60% misunderstood indication or dosing for at least 1 cardiac medication.

• Conclusion: NNH = 2 for medication confusion at hospital discharge.

*Mayo Clinic Proc. 2014; 89:1042*
Varenicline + NRT or Varenicline + Bupropion Are Better Than Varenicline Alone

- RCT of 450 long-term smokers to 12 weeks of varenicline (1mg BID) plus NRT patches (15mg X 16 hours/day) vs. varenicline plus placebo patches X 4 weeks
- Outcomes: At 24 weeks abstinence rates for 49% vs 33% (NNT = 7).
- Adverse events were similar in both groups.  
  
  *JAMA. 2014; 312:155.*

- RCT of 350 smokers used nicotine patch for 1 week then randomized to 12 weeks of varenicline alone vs. varenicline plus bupropion.
- Abstinence: self-report and expired CO. Drop-out rate was about 30% in each group.

  Outcomes
  - MEN: Abstinence: 40% for combination vs. 26% in varenicline alone (NNT=6).
  - Combination treatment was more effective in men who were smoking more than 20 cigarettes a day, but not for women or light smokers.

FOODS
Why **YOU** Must Counsel for Weight Loss

- Meta-analysis of 12 studies of Weight Loss Advice.

- Weight loss advice $\text{OR}=3.85$ (95% CI 2.71, 5.49; $P<0.01$) for weight loss.

- PCP advice on weight loss has a significant impact on patient change of behaviors related to their weight.

- “Providers should address weight loss with their overweight and obese patients”

- “*How do you feel about your weight?*”

What WE Eat: Too Many Carbs….

2010 2014
~2,400 ~2,550
51% 52%
33% 33%
16% 15%
August 13, 2015 Headline:
LOW FAT DIET BETTER FOR WEIGHT LOSS

Low Fat Diet vs Low Carb Diet
Low Fat or Low Carb?

• 19 Obese Adults 2700 Calorie baseline diet (50% carb, 35% fat, & 15% protein) x 5 days followed by either Low Carb vs Low Fat for 6 days
• Confined to a metabolic ward & exercised daily.
• 1900 calorie diets in random order during each of two inpatient stays

• Outcomes: Net Fat Oxidation (metabolic chamber) & Body fat loss
• CHO restriction \(\rightarrow\) ↑ fat oxidation and ↓ 53 ± 6 g/day of body fat
• Fat restriction \(\rightarrow\) fat oxidation unchanged and a ↓ 89 ± 6 g/day of fat loss, which was significantly greater than carbohydrate restriction (p = 0.002).

Cell Metabolism 22, 1–10, September 1, 2015
Calorie for Calorie, Dietary Fat Restriction Results in More Body Fat Loss than Carbohydrate Restriction in People with Obesity

Kevin D. Hall,1,* Thomas Bemis,1 Robert Brychta,1 Kong Y. Chen,1 Amber Courville,2 Emma J. Crayner,1 Stephanie Goodwin,1 Juen Guo,1 Lilan Howard,1 Nicolas D. Knuth,3 Bernard V. Miller III,1 Carla M. Prado,4 Mario Siervo,5 Monica C. Skarulis,1 Mary Walter,1 Peter J. Walter,1 and Laura Yannai1

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http://dx.doi.org/10.1016/j.cmet.2015.07.021

17 Authors; 19 Patients
Low Carb Diet Decreases Weight and Improves Framingham Risk Scores

- RCT of 148 obese adults: Low Carb (< 40g/day) vs Low Fat (< 30% calories from fat)
- No calorie intake goals were given. **Followed for over 1 year.**
- Energy intake in both diets fell from ~2000 calories/day to under 1500 calories/day
- In Low Carb diet: protein intake ↑ by ~8g/day & ↑ Fat intake
- In Low Fat Diet: Protein intake remained stable, ↓ in dietary fat

- 12 months:
  - **Weight reduction was greater in Low CHO group:** -3.5kg (p=0.002)
  - Fat Mass was lower in Low CHO -1.5% (p=0.011) with ↓ triglycerides & ↑ HDL

- Conclusion: Low Carbohydrate diet (< 40g/day) was more effective for both weight loss and cardiovascular risk factor reduction than low fat diets.
  
  *Ann of Inter Med* 2014; 161(5):309-318

**HOW DO WE COUNSEL FOR A LOW CHO DIET?**
Eat Fiber: One Simple Message for Weight Loss

• RCT 240 adults with metabolic syndrome to “increase fiber to ≥ 30g / day” or American Heart Association guidelines X 12 months.

• Outcome: AHA: - 2.7 kg vs Fiber – 2.1 kg Not Statistically Sig.

• Total caloric intake: AHA: ↓464 vs Fiber ↓200 calories

• Conclusion: Weight loss and heart outcomes can be achieved by
  One Simple Message: **eat > 30g of fiber a day.**

Regular Nut Consumption Improves Mortality

• Cohort studies (Nurses Health Study 76,000 women & Health Professionals study 42,000 men) Nut consumption by FFQ

• Nut consumption: ↓ all-cause mortality

• Nut consumption also correlated with ↑ physical activity, higher consumption of fruits and vegetables, limiting of tobacco use.

• Conclusion:
  • This trial confirms previous data that nut consumption → Decreases Mortality risk.

### Nut Intake Hazards Ratio for Death

<table>
<thead>
<tr>
<th>Nut Intake</th>
<th>Hazards Ratio for Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; Once a week</td>
<td>0.93</td>
</tr>
<tr>
<td>Once weekly</td>
<td>0.89</td>
</tr>
<tr>
<td>2-4 times / week</td>
<td>0.87</td>
</tr>
<tr>
<td>5-6 times / week</td>
<td>0.85</td>
</tr>
<tr>
<td>&gt; 7 times / week</td>
<td>0.80</td>
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</table>

How to Lose Weight RULES

--7-10 Vegetables & Fruits/day
--Lean Protein 3 times/day
--Nuts Daily
--16 Water Before ALL Meals
--Exercise, esp. after Meals

AVOID(NO): Juice, Soft Drinks, Breads, Rice, Pasta, Potatoes (even Sweet Potato)

Healthy does NOT Equal “Help You Lose Weight”
Digoxin Days are Almost Over

- SR & MA (19 Observational studies)
- Digoxin; > 235,000 A Fib & 91,000 CHF

Outcomes:
- 21% Increase in Relative Risk for death in people taking digoxin.
- AF: Increased risk was 29%; CHF: 14%

- The authors "calls for RCT of dose-adjusted digoxin therapy.... Until completed, digoxin should be used with great caution, particularly when administered for rate control in AF."

Eur Heart J 2015 Jul 21;36(28):1831-8
Digoxin Days are Almost Over

MA of > 40 trials (~1 million CHF & A Fib patients)

Digoxin vs placebo; **Mostly RCT’s**; some Observational studies

**Outcomes:** No effect (benefit) on mortality (slight ↓ in Admissions)

BMJ. 2015 Aug 30;351:h4451
It’s Sauna Time

- Prospective Finnish cohort study of 2,315 middle-aged men (42-60 years) x 20 Yrs
- After adjusting for CV risk factors
- Compared sauna use to risk of Sudden Death:
  - 2-3 times per week HR = 0.78
  - 4-7 times per week HR = 0.37 (p = 0.005).

- Best Outcome: sauna lasting > 19 minutes

*JAMA Inter Med.* 2015; 175(4):542-8
Where’s That Magazine?

- New Zealand Cohort study tracked waiting room magazines over 31 days.
- Magazines categorized as “non-gossipy” (i.e. *Time*, *The Economist*, etc.) vs. “gossipy” (> = 5 photos of celebrities on front cover (some over 10))
- 47/82 were < 2 Months of age

**Outcomes**
- At 31 days none of the “non-gossipy” magazines had disappeared.
- 96% of the “gossipy” magazines had disappeared
- Hazard ratio for “gossipy” magazine mortality = 14.51 (95% CI: 6.69-33.32).

**Conclusions:**
- People Steals the Gossipy Magazines
- Assumption that offices have old magazines is a form of selection bias

*BMJ. 2014; 349:g7262*
Enjoying Your Work

• Best Job In The World

• Take a Learner

• Hire a Scribe
HOW TO STAY CURRENT?

Twitter: @dominof

Or

Email Me: Frank.domino@umassmemorial.org
Summary

- Probiotics for Children ↓ Diarrhea, URI, ABX use
- Balloons for Serous Otitis Media
- No More Throat Culture or Fasting Lipid Panel
- MBS → Testicular Ca
- Teenage-hood (Not HPV Vaccine) ↑ STI Risk
- Ibuprofen = MSO4 for Fx
- Calculate Breast Cancer Risk & Discuss Rx
- Consider non-E2 for Hot Flushes (Rx, Music)
Summary

- Smoking Cessation: NRT & Bupropion + Varenicline
- Coffee and Saturated Fats are OK
- COUNSEL for Weight Loss
- Low Carb, High Fiber (7-10 Veg/Fruit) & Nuts
- Take a Sauna
- Buy Less Gossipy Magazines
EBM Updates From The Medical Literature

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