MYTH PANEL

WHOLE GRAIN DIALOGUE - FACT OR MYTH

INTERVENTION VS EPIDEMIOLOGY - SETTING THE STAGE

Dialogue – Intervention and Observational Studies

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Hierarchy of Human Studies for Evaluating Strength of Evidence of Disease Risk

Randomized clinical trials (RTCs) of disease outcomes

Prospective cohort studies of disease outcomes/surrogate endpoints

Randomized trials of surrogate endpoints

Retrospective studies of disease outcomes

Case reports

Adapted from Harris W S et al. J. Nutr. 2009;139:804S-819S
Overview of Evidence
Whole Grains and Disease Prevention

- Prospective observational studies of clinical endpoints
  - large and consistent body of evidence relating higher whole grain intake to reduced risk of CVD, diabetes, and colon cancer.

- Prospective observational studies of surrogate endpoints (e.g., weight, waist circumference, blood pressure, insulin resistance)
  - limited evidence but consistent with benefits of whole grains.

- RTCs - none

- Intervention trials of surrogate endpoints
  - in large part, do not support the observational findings
Why don’t the intervention trials support the observational studies?

- Possible conclusions based on evidence to date
  - Observational study findings are confounded/invalid as they are not supported by intervention trials
  - Intervention studies, as currently designed, are also susceptible to limitations/bias

- Inappropriate model for whole grain interventions
  - Treatment/therapeutic (drug) vs. prevention (observational)
  - Proposition - use of a therapeutic paradigm for nutritional interventions rather than a preventive paradigm based on observational studies is a large reason for the inconsistency between the whole grain interventions and observational findings and the main reason for the inconsistencies among the WG intervention trials.
Limitations of Nutritional Intervention Trials

• Treatment/therapeutic (drug) vs. prevention (observational) paradigm
  – Subjects: drugs – high risk (patients) vs. prevention – low risk (healthy)
  – Intervention period: drugs – short vs. prevention – long
  – Effect size: drugs – large vs. prevention – small for individual
  – Background exposure: drugs – rare vs. prevention – common

• Other issues specific to nutritional interventions
  – Reduced efficacy of nutritional interventions because of the use of drugs, which may have similar actions.
  – Adherence to treatment protocol
  – Heterogeneity of study populations/whole grain “treatments”
  – Appropriate definition of “placebo treatments”
Whole Grains and Health
What are the facts or myths?

- Current evidence from observational studies represent the truth and we need to design more appropriate intervention trials to better support that evidence.
- We need to rely on evidence from intervention studies of surrogate end points as results of observational studies are likely to be invalid.
- All existing evidence is based on studies with limitations and the role of whole grains in disease prevention is unclear.
- RTCs are necessary to determine if whole grains prevent cardiometabolic diseases and some cancers.