Disclosure
Currently on the speaker bureau's for the following companies related to this talk:

Ensure Enlive – Abbott
All Honoria to Big Heart Initiative charitable fund

...One Final Disclosure..

Treatment of Malnutrition and Heart Failure

A. Introduction
B. Preliminary Data
C. NOURISH Trial
D. Readmissions
E. Conclusions
OBJECTIVES

• Review the clinical impact of malnutrition and loss of lean body mass (LBM)

• Discuss the clinical and economic benefits of oral nutrition supplements (ONS)

• Present new scientific evidence of specialized ONS in the management of malnourished hospitalized patients


HOSPITAL ADMISSION

33% of severely malnourished patients and 38% of well-nourished patients experience nutritional decline.

Many patients continue to lose weight after discharge.

Patients with weight loss have an increased risk for readmission.

HOSPITAL STAY

30% to 55% of hospital patients are malnourished upon admission.

HOSPITAL DISCHARGE

HOSPITAL READMISSION

DISEASE ASSOCIATED MALNUTRITION IS ASSOCIATED WITH ILLNESS, INJURY, AND HOSPITALIZATION

Risk of dying increases when food intake is limited by illness or injury.

Loss of lean body mass delays recovery and impedes rehabilitation.

Hospitalization itself often worsens nutritional status.

Some evidence indicates increased risk for infection, especially if nutrition protocol is suboptimal.


MALNUTRITION NEGATIVELY AFFECTS PATIENT OUTCOMES

Malnutrition

Wound Healing
Infections
Complications
Convalescence
Hospital Readmissions
Mortality
Treatment
Length of Stay (LOS)
Cost
Quality of Life


MALNUTRITION SARCOPENIA SYNDROME

- Sarcopenia
- Fatality
- Deconditioning
- Sarcopenic Obesity
- Cardiac Cachexia
- Cancer Cachexia
- ESRD/CKD
- COPD
- ICU Acquired Weakness
- HIV Cachexia

- Protein calorie malnutrition
- Undernutrition
- Hospital acquired malnutrition
- Disease related malnutrition

Morbidity
Mortality
Economic Impact

MALNUTRITION SARCOPENIA SYNDROME

WHAT IS LEAN BODY MASS (LBM)?

Muscles
Organs
Bone

- LBM accounts for 75% of normal body weight
- Muscle is the largest component of LBM

Functions of LBM include:
- Mobility
- Balance
- Generation of heat (energy)
- Protein / amino acid pool for skin, immune & digestive systems
- Survival during periods of stress

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Malnutrition
PROGRESSIVE LOSS OF LBM / MUSCLE MASS OCCURS NATURALLY WITH AGE

Age-related loss of muscle mass, strength and/or functionality is called Sarcopenia.

5. Vandewoude MFJ, et al. Malnutrition

100% of Muscle Mass
Age 25yrs 40yrs 70yrs 80yrs
8% loss Per decade from 40-470
Per decade after age 70 15% loss
100% 40% 50% 60% 70% 80% 90%
<70%: Zone where risk of death is high

Syndrome: is this the future of nutrition screening and assessment for older adults.

BED REST, AGE AND HOSPITALIZATION INCREASE LOSS OF LBM

Healthy Young Healthy Elderly Elderly Inpatients

Healthy Young Healthy Elderly Elderly Inpatients

Approximate total loss of LBM (time in days)

1 lb (28) 2.2 lb (10) 2.2 lb (3)

INTERVENTIONS TO MITIGATE LBM LOSS

• Exercise/activity
• Dietary intervention
  – Dietary Proteins
  – ONS
  – Targeted nutrients
  • amino acids
  • beta-hydroxy-beta-methylbutyrate (HMB)
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NUTRITION INTERVENTIONS LEAD TO IMPROVED OUTCOMES

Nutrition intervention can produce positive results to improve patient care quality and reduce overall costs.

- 28% reduction in avoidable readmissions
- 2-day reduction in average length of stay
- 23% reduction in pressure ulcer incidence
- 14% reduction in overall complications (e.g., infections, anemia, etc.)

ONS use is associated with reduction in mortality in select patients (e.g., elderly malnourished patients).


ORAL NUTRITION SUPPLEMENTS PROVIDED DURING HOSPITALIZATION WAS ASSOCIATED WITH:

- 21% decrease in length of stay (2.3 days)
- 21.6% decrease in episode costs ($4734)
- 6.7% decrease in probability of 30-day readmissions

(Notes: Figures based on hypothetical calculations and utilized data from various studies.)
TARGETED NUTRIENT:
ß-HYDROXY ß-METHYLBUTYRATE (HMB)

Bioactive metabolite of leucine:
• Occurs naturally in human muscle cells
• Found in small amounts in many foods (e.g., avocado, grapefruit, catfish)

Exerts its effects through protective, anticytotic mechanisms and has been shown to:
• Decrease protein degradation via NFkB downregulation
• Preserve muscle mass in older adults during extended bed rest
• Stabilize muscle cell membrane

EFFECT OF HMB ON LEAN BODY MASS DURING 10 DAYS OF BED REST IN OLDER ADULTS

• Supplements: 2 sachets/day with 4 g maltodextrine, 200 mg Ca and flavoring agents
  - HMB group: 1.5 g Ca+HMB
  - Controls: no addition

• Diet stabilization to 0.8 g protein/kg BW/day and (calculated) energy requirements

• Bed rest for 10 days with only wheelchair for toileting or showering

• Prophylactic measures
  - D4Dimer test, TED hose and daily checking
  - Constant monitoring by nursing staff and daily physical by physician

• Rehabilitation for 8 weeks with resistance exercise training: 3 days/week

HMB PRESERVES LBM
EFFECT OF HMB ON MUSCLE STRENGTH IN HEALTHY MEN AND WOMEN

Non-exercising Groups

HMB Placebo

p=0.04

HMB — SAFE AND WELL TOLERATED

Review article and meta-analysis of HMB clinical studies published in 2013
n=39 articles

Conclusions:
• 3 g/day (CaHMB) efficacious dose
• Effective in preventing exercise-related muscle damage
• Effective in preventing muscle loss during chronic diseases
• No safety concerns

Molfino et al., Amino Acids. 2013 Dec;45(6):1273-492

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Readmission and Mortality in Malnourished, Older, Hospitalized Adults Treated With a Specialized Oral Nutritional Supplement: A randomized clinical trial


NOURISH STUDY OBJECTIVE

NOURISH: Nutrition effect on Unplanned Readmissions and Survival in Hospitalized patients


Statistical Analysis:

Intention-to-treat, p < 0.05 statistical significance
SUBJECTIVE GLOBAL ANALYSIS

• Evaluated nutritional and medical history and changes
• Validated in healthy and disease populations
• The gold standard for diagnosing malnutrition


Study Results

BASELINE DEMOGRAPHIC AND CLINICAL CHARACTERISTICS SHOWED NO STATISTICAL DIFFERENCE BETWEEN GROUPS

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>HP-HMB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr, Mean ±SEM)</td>
<td>78.14 ±0.49</td>
<td>77.72 ±0.47</td>
</tr>
<tr>
<td>Charlson Comorbidity Score (Mean ±SEM)</td>
<td>2.05 ±0.08</td>
<td>2.12 ±0.08</td>
</tr>
<tr>
<td>Government sponsored insurance, n(%)</td>
<td>278(89%)</td>
<td>276(89%)</td>
</tr>
<tr>
<td>Income &lt; $25,000/yr, n(%)</td>
<td>130(42%)</td>
<td>154(49%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender and Race</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
</tr>
<tr>
<td>41.1%</td>
</tr>
</tbody>
</table>

BASELINE DEMOGRAPHIC AND CLINICAL CHARACTERISTICS SHOWED NO STATISTICAL DIFFERENCE BETWEEN GROUPS

<table>
<thead>
<tr>
<th>Primary admission Dx</th>
<th>Control</th>
<th>Placebo</th>
<th>HP4HMB</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMI</td>
<td>13 (23.6%)</td>
<td>10 (18.2%)</td>
<td>10 (18.2%)</td>
</tr>
<tr>
<td>CHF</td>
<td>157 (100%)</td>
<td>157 (100%)</td>
<td>157 (100%)</td>
</tr>
<tr>
<td>COPD</td>
<td>24 (11.2%)</td>
<td>24 (11.2%)</td>
<td>24 (11.2%)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>19 (9.7%)</td>
<td>19 (9.7%)</td>
<td>19 (9.7%)</td>
</tr>
</tbody>
</table>


PRIMARY PATIENT ADMITTING DIAGNOSIS AND COMORBIDITIES

<table>
<thead>
<tr>
<th>Comorbidities per Charlson Index</th>
<th>N (%)</th>
<th>Myocardial infarction</th>
<th>Congestive heart failure (CHF)</th>
<th>Chronic pulmonary disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>AM</td>
<td>15</td>
<td>13 (86.7%)</td>
<td>13 (86.7%)</td>
<td>10 (66.7%)</td>
</tr>
<tr>
<td>CHF</td>
<td>35</td>
<td>15 (42.9%)</td>
<td>15 (42.9%)</td>
<td>15 (42.9%)</td>
</tr>
<tr>
<td>COPD</td>
<td>24</td>
<td>11 (45.8%)</td>
<td>11 (45.8%)</td>
<td>11 (45.8%)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>19</td>
<td>9 (47.4%)</td>
<td>9 (47.4%)</td>
<td>9 (47.4%)</td>
</tr>
</tbody>
</table>


PRIMARY COMPOSITE ENDPOINT

Kaplan-Meier Survival Curve: Composite Endpoint of 90-Day Readmission and Mortality

**PRIMARY COMPOSITE ENDPOINT**

Kaplan-Meier Survival Curve: Realisation

Placebo vs HP4HMB

\[ p = 0.749 \]

Days post-discharge


Proportion Kaplan-Meier Survival Curve: Readmission

**PRIMARY COMPOSITE ENDPOINT**

Kaplan-Meier Survival Curve: Mortality

Placebo vs HP4HMB

\[ p = 0.013 \]

Days post-discharge


Proportion Kaplan-Meier Survival Curve: Mortality

HP-HMB WAS ASSOCIATED WITH 50% REDUCTION IN MORTALITY

Post hoc estimation of the number needed to treat (NNT)

\[ p = 0.049 \]

\[ p = 0.018 \]

\[ p = 0.020 \]

6.2 8.7 9.7 2.9 4.2 4.8 14121086420

Day 30 Day 60 Day 90

Percent Mortality Control HP4HMB Placebo

\[ \text{To prevent 1 death was 20.3 (95% CI, 10.9 to 121.4).} \]
HP-HMB IMPROVED NUTRITIONAL STATUS

By day 90, HP4HMB had higher odds of better nutritional status as assessed by SGA (OR = 2.04, P = 0.009).


Baseline Day30 Day60 Day90

HP-HMB IMPROVED WEIGHT GAIN

Change in body weight (mean change in kg)


Baseline Day30 Day60 Day90

HP-HMB INCREASED SERUM VITAMIN D LEVEL

“DEUTZ ET AL. SHOWED THAT 20 PATIENTS SHOULD BE TREATED TO SAVE 1 DEATH [6]. THEIR DECISION TO PROVIDE THIS INFORMATION IS INTERESTING SINCE IT ASSOCIATES NUTRITIONAL SUPPORT TO PHARMACOLOGICAL THERAPIES, AND IT IS RELEVANT SINCE THE NNT FOR THIS SPECIFIC ONS IS QUITE ENCOURAGING. INDEED, SCHORK HAS RECENTLY REVIEWED THE NNT FOR SOME BLOCKBUSTER DRUGS, AND IT IS SURPRISING TO NOTE THAT THE NNT FOR OSEMPREZOLE IS 24 [8].”

**HMB**

- 350 Cal per 8-fl-oz serving
- 1.5 grams of CaHMB
- 20 grams of high-quality protein
- 120% Daily Value of vitamin D
- 26 vitamins and minerals
- Omega-3s (plant-based ALA)
- Antioxidants (vitamins C and E and selenium)
- 3 grams of fiber

**SUMMARY**

- Among hospitalized patients, disease associated malnutrition and the loss of lean body mass is prevalent and costly
- Nutritional interventions including oral nutritional supplements help improve patient outcomes
- The use of a high-protein oral nutritional supplement containing beta-hydroxy-beta-methylbutyrate is associated with improved clinical and nutritional outcomes in malnourished hospitalized patients with cardio-pulmonary disease
WHAT CAN YOU DO FOR YOUR MALNOURISHED PATIENTS?

Standardize Nutrition Intervention for Improved Patient Care

**SCREEN**
- All Patients
  - Identify risk of
    - Malnutrition
    - LBM loss

**INTERVENTE**
- Early
  - Recommend two ONS per day
  - Nutrition therapy

**FOLLOW-UP**
- Compliance
  - Reassess to improve patient outcomes

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Optimizing the Nutrition Care Process to Reduce 30-day Readmissions
CMS REDUCES PAYMENTS FOR PREVENTABLE READMISSIONS

- 2,592 hospitals were penalized by the Centers for Medicare and Medicaid Services (CMS) in fiscal year (FY) 2015.
- Fines estimated by CMS in FY 2015 — $420 million.
- Penalties increased in FY 2015 to 3%: A hospital with $100 million in Medicare payments could be penalized $3 million.
- 75% of hospitals subject to the Hospital Readmission Reduction Program are being penalized.
- Hardest hit hospitals are in New Jersey; New York; Washington, DC; Arkansas; Kentucky; Mississippi; Massachusetts; and Illinois.


EVIDENCE THAT NUTRITION INTERVENTION DECREASES READMISSIONS

Hospital patients who received dietary counseling plus oral nutritional supplements (ONS) experienced significantly fewer readmissions (P = 0.041).

<table>
<thead>
<tr>
<th>Group</th>
<th>Readmission Rates (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>48%</td>
</tr>
<tr>
<td>ONS Only</td>
<td>48%</td>
</tr>
<tr>
<td>Counseling Only</td>
<td>16.5%</td>
</tr>
<tr>
<td>Food Only</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

30-day readmission rates decreased from 16.5% to 7.1% after institution of comprehensive nutrition pathway from inpatient to post-discharge.

Patients who received ONS (≤995 kcal/day) in addition to food for 6 weeks had fewer readmissions: 29% who consumed ONS vs 40% who ate food only.


A Rapid, Comprehensive Oral Nutritional Supplement Quality Improvement Program (QIP) Reduced 30-day Readmission in Malnourished Hospitalized Patients

Sriram K et al., JPEN J Parenter Enteral Nutr 2016; 40, pp 24-35.

This trial was registered with U.S. National Institutes of Health and U.S. National Library of Medicine on www.ClinicalTrials.gov: NCT02262429.
STUDY SETTING: ADVOCATE HEALTH CARE SYSTEM

- The largest health care provider in Illinois
- One of the largest accountable care organizations (ACO) in the US
- 250 sites of care and 12 hospitals
- Over 2 million patients seen annually
- Five Level I trauma centers, three Level II trauma centers
- Not-for-profit, mission-based health system
- A leader in population health management and coordinated care

RESEARCH QUESTION AND PRIMARY ENDPOINT

- Study Hypothesis: Administration of a rapid, automatic ONS intervention from screening to discharge will decrease 30-day readmission rate by 20% or more and yield superior cost-effectiveness compared with existing ONS protocol in patients at risk for malnutrition
- Primary Endpoint: Incidence of nonelective readmission 30-days post discharge
- Patient Population: 18+, any primary diagnosis, risk for malnutrition (Malnutrition Screening Tool [MST] score ≥2)

MALNUTRITION SCREENING TOOL (MST)

- MST is a validated screening tool and evaluates weight loss and appetite as two criteria most indicative of malnutrition risk
- The set of questions helps to quantify patients malnutrition risk level

Malnutrition Screening Tool

Sriram K et al., JPEN J Parenter Enteral Nutr 2016; 40, pp244-25.
DIFFERENCES BETWEEN QIP+ AND QIP

<table>
<thead>
<tr>
<th>Differences of QIP+ and QIP Programs</th>
<th>QIP+</th>
<th>QIP</th>
</tr>
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<tbody>
<tr>
<td>MST is a part of EMR</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>RN completes MST</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>ONS ordered by MD, RN, or RD</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Discharge consultation</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Time to MD consultation per patient</td>
<td>24 - 48h</td>
<td>24 - 48h</td>
</tr>
<tr>
<td>Discharge planning instructions</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Discharge materials including coupons and literature</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Standard post-discharge phone calls (≤72 hours)</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Nutrition-focused post-discharge questions on phone calls</td>
<td>√</td>
<td>√</td>
</tr>
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MD = Physician; RN = Registered Nurse; EMR = Electronic Medical Record

RESULTS FOR QIP SITES (N=769)

Readmission Rate: 20%

Pre-QIP
- No validated screening tool
- No early intervention
- No formalized nutrition discharge education
- No post-discharge reminders about nutrition

QIP
- Validated screening tool (MST) integrated into EMR
- Targeted ONS intervention in 24-48 hours
- No formalized nutrition discharge education
- No post-discharge reminders about nutrition

18% Reduction vs Baseline

p < 0.01

Sriram K et al., JPEN J Parenter Enteral Nutr 2016;40.

RESULTS FOR QIP+ SITES (N=500)

Readmission Rate: 20%

Pre-QIP
- Nonvalidated screening tool
- No early intervention
- No formalized nutrition discharge education
- No post-discharge reminders about nutrition

QIP+
- Nonvalidated screening tool
- No early intervention
- No formalized nutrition discharge education
- No post-discharge reminders about nutrition

25% Reduction vs Baseline

p < 0.01

Sriram K et al., JPEN J Parenter Enteral Nutr 2016;40.
RESULTS FOR ALL QIP AND QIP+ SITES

<table>
<thead>
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<th>Screening</th>
<th>Pre-QIP</th>
<th>QIP</th>
<th>QIP+</th>
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<td>Readmission Rate</td>
<td>20%</td>
<td>16.4%</td>
<td>15.6%</td>
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- **Screening Interventions**:
  - No validated screening tool
  - No validated screening tool
  - Validated screening tool (MST) integrated into EMR

- **Education**:
  - No education
  - Exchange education
  - Ongoing education about nutrition

18% Reduction vs Baseline postdischarge

- **Post-Discharge**:
  - No reminders about nutrition
  - Formalized nutrition discharge education with coupons
  - Formalized nutrition discharge education with coupons

22% Reduction vs Baseline. \( p < 0.01 \)

18% Reduction vs Baseline. \( p < 0.01 \)

ECONOMIC MODEL OF STUDY RESULTS

**QIP+ SITES** (500 patients enrolled)
- 100 expected – 78 observed = 22 prevented readmissions x $18,900 average readmission cost = $407,000

**QIP SITES** (769 patients enrolled)
- 154 expected – 126 observed = 28 prevented readmissions x $18,900 average readmission cost = $518,000

Total 6-Month Savings = $925,000*  
Projected Annual Savings = $1,850,000

CONCLUSIONS

- A comprehensive ONS QIP reduced 30-day unplanned hospital readmissions among hospitalized patients at risk of malnutrition.
- Keys to success:
  - Multidisciplinary team collaboration and follow-up
  - Implementation of a validated nutrition screening tool in EMR
  - Immediate provision of ONS
  - Ongoing patient and caregiver education in hospital and at discharge
  - Post-discharge questions related to ONS
  - Ongoing provider education
  - Sustained provider and administrative program support

*During the period of this study involving 4 hospitals.†Based ONLY on application of current, limited QIP protocol.
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Treatment of Malnutrition and Heart Failure Conclusions

A. Malnutrition is a big problem in patients with Heart Failure
B. Therapy can decrease mortality and readmissions
C. We should screen for malnutrition and treat Heart Failure patients that qualify