Scientific Publications Compendium

2016·**2017**·2018

Nestlé HealthScience

www.nestlehealthscience.com
April 2018

Prologue

Dear Reader,

In 2017, Nestlé Health Science contributed to a number of scientific publications, covering a broad spectrum of the clinical conditions our company focuses on. I am now pleased to share with you this booklet, which highlights these publications' summaries.

As an innovative health science company, we strongly believe in investing in and leveraging leading-edge science. We strive to forge a new industry based on inherently safe nutritional therapies, which bring relevant quality of life benefits and proven clinical and health economic value. Our aim is to fully leverage the role of nutrition in changing the course of health for consumers and patients.

I also take this opportunity to thank all the experts involved in this work, namely Healthcare Professionals, Institutions and Nestlé Health Science colleagues. Our meaningful scientific partnership will positively impact patients and consumers' lives.

I hope you will enjoy the read.

Best regards,

Moreno Perugini, MBA, MHE, MPA, CPP
Global Head of Medical Affairs, Market Access and Pricing
Nestlé Health Science

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Study Summary

Formula Switch Leads to Enteral Feeding Improvements in Children With Developmental Delay

Minor G, Ochoa Gautier JB, Storm H, Periman S

Glob Pediatr Health. 2016 Dec 21;3:1-6

https://www.ncbi.nlm.nih.gov/pubmed/28229094

• Background

Enteral nutrition is often necessary in children with developmental delay. The objective of this study was to assess improvements in tolerance parameters.

• Methods

The study population comprised children with developmental delays who had failed to reach nutritional goals on intact protein formulas and were thus switched to a 100% whey peptide-based formula. Medical records were retrospectively assessed for feeding tolerance parameters, volume and calorie goals, and symptomatic medication use before and after the switch.

• Results

Thirteen children with a primary diagnosis of developmental delay (mean ± standard deviation age: 8.4 ± 4.6 years) were included in the analysis. Ten were fed through a gastrostomy tube. An improvement in feeding tolerance was observed for 12 children (92%), and 9 of these improved within a week of the formula switch. Improvements in feeding tolerance were noted for vomiting (86%), gagging and retching (75%), high residual volumes (63%), constipation (43%), diarrhea (100%), and weight gain (100%).

• Conclusion

In children with developmental delay, a switch to a peptide-based formula can markedly reduce feeding intolerance.

Study Summary

Protein Requirements of the Critically Ill Pediatric Patient

Coss-Bu JA, Hamilton-Reeves J, Patel JJ, Morris CR, Hurt RT

Nutr Clin Pract. 2017 Apr;32(1_suppl):128S-141S

https://www.ncbi.nlm.nih.gov/pubmed/28388381

• Background

Determining protein requirements in health and ill children is challenging and complex. Protein requirements can be expressed as average requirements but also as a reference intake that will satisfy the needs of 97.5% of the population.

• Methods

Invited review of protein needs in healthy and sick children and a detailed discussion of the protein metabolism during critical illness.

• Results

In healthy children, the amount of protein supplied should enable adequate growth during infancy and childhood. A continuous supply of nutrients is more important in children than in adults. In critically ill children, overall protein turnover is greater as a result of elevated whole-body protein synthesis and degradation. This is associated with poor growth failure, malnutrition, lean body mass loss, and a poorer clinical prognosis. Hence, critically ill infants and younger children require a greater quantity of protein (normalized against body weight) than older children. In critically ill children, enteral provision of energy and protein content is associated with better survival.

• Conclusion

Critically ill children require a higher protein intake. The possible adverse events associated with increased protein intake must be monitored. Future research (using randomized design) should investigate the relationship between protein intake and patient outcomes (lean body mass, mechanical ventilation, muscle parameters, mortality, and length of stay in the ICU or in hospital overall, etc.).

Study Summary

Meeting Pediatric Nutrition Needs with an Enteral Formula Containing Real Food

Minor G, Cekola P, Cohen S, Huhmann M

Congress Abstract - FNCE 2017 - Chicago

http://jandonline.org/article/S2212-2672(17)30878-X/pdf

• Background

In children with developmental disabilities and feeding problems, enteral nutrition (EN) may can support adequate growth and development. Some commercially available enteral formulas include "real food" ingredients in response to requests from parents and healthcare professionals.

• Methods

This was a prospective observational study of a pediatric population receiving EN due to developmental delay or other neurological disorders. The primary objective was to establish whether an EN formula containing real food (Compleat® Pediatric) could meet the patients' estimated nutrition needs vs intake on an standard formula. Each participant's parents recorded the intake of standard EN formula for one day and then switched to Compleat® Pediatric formula for 7 days. Gastrointestinal parameters and adverse events were assessed.

• Results

A total of 21 children were included (mean age: 6.4 years; males: 57%) and 20 completed the study. The mean calorie intake was similar in the standard and Compleat® Pediatric groups (1288 vs. 1205 kcals/day, respectively), as was the mean protein intake (38 vs. 48 g/day, respectively). At least 90% of the calorie target was achieved for 12 children receiving Compleat® Pediatric, and the other 8 children achieved 59 to 85% of the target*. The "real food" formula was well tolerated, and no serious adverse events were reported.

• Conclusion

An EN formula containing real food ingredients provided much the same nutritional intake as a standard formula in children with neurological diagnoses and was not associated with increased GI symptoms.

** Corresponding data for the standard group were not provided in the abstract*

Study Summary

Pediatric Nutrition Needs Met With A High Calorie Peptide-based Enteral Formula

Chen L, Cekola P, Telch J, Cohen S, Huhmann M

Congress Abstract - FNCE 2017 - Chicago

http://jandonline.org/article/S2212-2672(17)30885-7/fulltext

• Background

In patients with neurological disorders, impaired gastrointestinal function is associated with an increased risk of malnutrition and thus negative effects on growth and development. Enteral nutrition (EN) with whey-peptide-based products may be of benefit in this context.

• Methods

A prospective, observational study examined the ability of a calorie-dense (1.5 kcal/mL) whey peptide EN formula (Peptamen® Junior 1.5) to meet calorie goals (>90% of the target for at least 14 days) in children with developmental delay and impaired gastrointestinal function. Stools, vomiting, gas, pain, and adverse events were also assessed. After a three-day baseline period on the usual formula, the participants were switched to Peptamen® Junior 1.5 for 21 days.

• Results

The study included 8 children (3 girls, 5 boys; average age 8 years). Five participants met the calorie goal and 3 met 73-81% of the calorie goal. All participants met protein goals. The calorie intake increased from 1085 to 1345 kcals/d during the EN, and the protein intake increased from 36 to 41 g/d. The EN formula was well tolerated.

• Conclusion

Peptamen® Junior 1.5 EN formula was associated with an increase in protein and calorie intake in a small sample of children with developmental delay and impaired gastrointestinal function.

Study Summary

Pooled Analysis of the Cow's Milk-Related-Symptom-Score(CoMiSS™) as a Predictor for Cow's-Milk-Related-Symptoms

Vandeplas Y, Steenhout P, Järvi A, Garreau AS, Mukherjee R

Pediatr Gastroenterol Hepatol Nutr. 2017 Mar; 20(1): 22–26

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5385303/

• Background

The diagnosis of cow's milk allergy is challenging (especially for primary healthcare providers) but can be aided by the use of reliable diagnostic tools.

• Methods

The predictive value of the cow's-milk-related-symptom-score (CoMiSS™) was evaluated by pooling the data from three clinical trials in infants. A logistic regression model was used to analyze the pooled results of the challenge test and the CoMiSS™ after 1 month of a diet lacking intact CM protein (with adjustment for the baseline CoMiSS™ score) and to assess the predictive value of the change from baseline in the CoMiSS™.

• Results

Children with a low CoMiSS™ at 1 month had a significant risk of a positive challenge test (odds ratio [95% confidence interval] = 0.83 [0.75-0.93]; p=0.002). The change in CoMiSS™ from baseline to month-1 was predictive of the result of the challenge test at month-1.

• Conclusion

The pooled results of three trials in allergic patients confirm that CoMiSS™ may be a specific and sensitive awareness tool to select infants with suspected CM-related symptoms. However, a prospective validation trial in a population of infants without CM-related symptoms is needed.

Symposium Summary

EAACI Satellite Symposia Proceedings: Controversies on Special Products for Managing Cow's Milk protein Allergy in Infants - Safety and Suitability

Meyer R, Kuslys M, Muraro A, Høst A

Summary of a EAACI Satellite Symposium on 18th June 2017

http://emjreviews.com/therapeutic-area/allergy-immunology/controversies-on-special-products-for-managing-cows-milk-protein-allergy-in-infants-safety-and-suitability/

• Background

The EAACI Task Force on special products for cow's milk protein allergy (CMPA) was established in 2016 to focus on levels of evidence in the treatment of infants with this condition. The symposium's speakers addressed issues regarding the definition, nature and testing of extensively hydrolysed formula (eHF) preparations.

• Methods

A summary of a satellite symposium.

• Results

First, Dr Rosan Meyer highlighted differences in the two main definitions for "hypoallergenic" formulas - notably the lack of supporting evidence to show that a <1% immune-reactive protein threshold would prevent a clinical reaction, and that the product should have no peptides >1.5 kDa. Lactose content is less of a problem than expected. An eHF should comply with EAACI guidelines, meet growth and nutritional needs, and have a suitable micronutrient content. Dr Martinas Kuslys discussed peptide profiles of eHFs: the casein concentrations and molecular weight (MW) distributions vary markedly, and the percentage of peptides with MW >1.2 kDa varied from 1 to 36%. The degree of hydrolysis alone is not enough to characterise eHFs. Professors Antonella Muraro and Professor Arne Høst closed the meeting by emphasizing that although allergenicity can reduced by enzymatic hydrolysis, heat treatment, and/or ultrafiltration, not all products for infants with CMPA are safe and effective. Strict labelling and quality criteria should be established and a European database of products for CMPA should be created.

• Conclusion

The composition of eHFs varies markedly. Stricter labelling and quality criteria should be established, and a European database of products for CMPA should be created.

Study Summary

Diagnosis and management of cow's milk protein allergy – How big is the gap between ideal and reality? A quality-of-care survey in Europe

Werkstetter K, Chmielewska A, Dolinšek J, Estourgie-van Burk F, Korponay-Szabó I, Kurppa K, Mišak Z, Papadopoulou A, Popp A, RibesKoninckx C, Szentes B, Szitanyi P, Theisen A, Troncone R, Veres G, West C, Koletzko S

Congress Poster - PAAM 2017 - London

http://www.eaaci.org/meetings/PAAM2017-Abstracts/abstracts/PAAM2017_P66.pdf

• Background

In 2012, the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) published guidelines on the diagnosis and management of cow's milk protein allergy (CMPA). However, it remained to be seen whether these recommendations had been implemented in primary care.

• Methods

This was an anonymous, online, multiple-choice, quality-of-care survey of CMPA management by pediatricians and/or general practitioners in Croatia, Czech Republic, Finland, Germany, Greece, Hungary, Italy, Poland, Romania, Slovenia, Spain, Sweden and the Netherlands.

• Results

A total of 2551 physicians (women: 72%; pediatricians: 86.8%) completed the survey. For the case a 10-month old infant with chronic diarrhea and failure to thrive, only 32% correctly chose an elimination diet and a challenge procedure. For an infant diagnosed with CMPA but who refused an extensively hydrolyzed formula, only 63% correctly stated that an amino-acid-based formula is acceptable, and only 51% correctly stated that a soy-based formula is acceptable. For an exclusively breast-fed 5-month-old infant developing swelling of lips and eyelids upon the second bottle of standard formula, only 26% answered correctly. Other questions also gave low proportions of correct interpretations.

• Conclusion

Uptake and implementation of the ESPGHAN's 2012 guidelines on the management of CMPA should improve – notably with regard to test procedures, elimination diets, and types of infant formula.

Study Summary

Treatment patterns in patients with cow's milk protein allergy (CMPA) in a German sickness fund database

Dive-Pouletty C, Järvi A, Pignot M, Cholmakow-Bodechtel C, Scheider M

Congress Poster - PAAM 2017 - London

http://www.eaaci.org/meetings/PAAM2017-Abstracts/abstracts/PAAM2017_D46.pdf

• Background

In Europe, incident cow's milk protein allergy (CMPA) affects between 1% and 7% of under-3 infants, and is associated with a range of gastrointestinal, skin and respiratory symptoms. According to the latest guidelines, first-line dietary management of CMPA should be based on extensively hydrolyzed formula (eHF). Amino-acid-based formula (AAF) is reserved for severe cases

• Methods

This was an analysis of a German prescription reimbursement database from Q4-2007 to Q1-2015, with the objective of assessing prescribing patterns for eHFs and AAF in CMPA. The inclusion criteria were age 0-3 years, ICD-10 codes compatible with CMPA, and treatment with formula at least 2 months.

• Results

Out of a total of 332,012 under-3 infants in the database, 564 were analyzed (first-line treatment with eHF in 38% and with AAF in 62%; males: 58% in the eHF group and 66% in the AAF group). The mean age at first prescription was 41.3 weeks in the eHF group and AAF 41.5 weeks in the AAF group. 90% of the eHF group stayed on that formula for a mean of 34 weeks (median: 28 weeks). 97% of the AAF group stayed on AAF for an average of 43 weeks (median: 30 weeks). The eHF and AAF group did not differ significantly with regard to demographics and ICD-10 codes (a proxy for efficacy).

• Conclusion

In Germany, too few infants are prescribed with eHF as a first-line treatment. First-line treatment with eHF appeared to be more cost-effective.

Study Summary

A prospective cohort of patients receiving exclusive enteral nutrition (EEN) confirms high clinical response rates after 8 weeks of treatment: initial results from the BIG study

Logan M, Clark C, Duncan H, Richmond L, Barclay A, Hansen R, Flynn D, Tayler R, Gerasimidis K, Russell R

Congress Abstract (G-P-283) - ESPGHAN 2017 - Prague

http://journals.lww.com/jpgn/toc/2017/04001

• Background

Exclusive enteral nutrition (EEN) is the first-line treatment for active luminal Crohn's disease (CD) in children.

• Methods

Pediatric patients diagnosed with CD (according to clinical, endoscopic and histological criteria) participated in the prospective Bacteria & Inflammation in the Gut study between August 2014 and June 2016. The objective was to assess the efficacy (according to the weighted paediatric Crohn's disease activity index score, wPCDAI) of first-line polymeric EEN (Modulen® or Paediasure®) administered for 8 weeks. Levels of inflammation markers and haemoglobin were also recorded.

• Results

A total of 41 patients (12 girls, 29 boys; median [IQR] age at diagnosis: 12.3 [10.0-14.7] years) participated. 34 (76%) patients presented with disease in both small intestine and colon. Forty participants had a wPCDAI >12.5 at baseline (median [IQR] = 38.8 [21.9-57.5]). Following treatment with Modulen® (n=40) or Paediasure® (n=1), 10 participants showed symptom worsening or poor tolerability of EEN unable. After treatment, 31 of the 41 (76%) patients achieved clinical remission (wPCDAI<12.5). Before treatment initiation, 63% of participants had a least one abnormal inflammatory marker level. EEN was associated with significant improvements in the ESR (p=0.012), CRP (p=0.004), albumin (p=0.0001), and (especially in responders) calprotectin parameters (p=0.006).

• Conclusion

An 8-week course of treatment with polymeric EEN was associated with clinical remission in 76% of patients and with significant falls in blood inflammation marker levels.

Study Summary

Nutritional status of older patients with oropharyngeal dysphagia in a chronic versus an acute clinical situation

Carrión S, Roca M, Costa A, Arreola V, Ortega O, Palomera E, Serra-Prat M, Cabré M, Clavé P

Clin Nutr. 2017 Aug;36(4):1110-1116

https://www.ncbi.nlm.nih.gov/pubmed/27499393

• Background

Oropharyngeal dysphagia (OD) in older patients with either chronic or acute conditions is associated with a high prevalence of malnutrition and sarcopenia.

• Methods

In a study of chronic and acute clinical situations, the investigators assessed nutritional status in older (over-70) patients with OD. Three groups were considered: patients with chronic neurological or age-related diseases, patients with acute community-acquired pneumonia (using videofluoroscopy), and a control group of people free of OD. Data on nutritional status (according to the Mini Nutritional Assessment (MNA®)), anthropometric parameters, biochemistry, body composition (using bioimpedance) and functional status (according to the Barthel index) were assessed.

• Results

In the group with OD and chronic conditions, 51.1% of the patients had a MNA® score ≤23.5 and 16.7% had sarcopenia. Other conditions included muscle and fat loss, muscle weakness, body weight loss and intracellular water depletion. Higher levels of viscosity were required for safe swallowing. In the acute group with OD and CAP, 69.5% of the patients had an MNA® score ≤23.5, and 29.4% had sarcopenia. Muscle and fat depletion was particularly severe.

• Conclusion

In a chronic setting, OD is associated with poor nutritional status and retention of oropharyngeal residue at a spoon-thick viscosity. In an acute (community-acquired pneumonia) setting with OD, inflammation and protein deficiency are additionally present.

Study Summary

The Effects of Aspirated Thickened Water on Survival and Pulmonary Injury in a Rabbit Model

Nativ-Zeltzer N, Kuhn M, Imai D, Traslavina R, Domer A, Litts J, Adams B, Belafsky P

Laryngoscope. 2018 Feb;128(2):327-331

https://www.ncbi.nlm.nih.gov/pubmed/28730738

• Background

Liquid thickeners are often used as an additive for feeding patients with dysphagia. However, aspirated liquid thickeners may damage the lungs.

• Methods

In prospective small animal study, adult New Zealand White rabbits (n = 24) were divided into three groups of eight and made to aspirate 1.5 mL/kg of (i) water, (ii) xanthan-gum-thickened water or (iii) and cornstarch-thickened water for three consecutive days. The effects on survival and pulmonary histopathology (after euthanization on day 4) were recorded.

• Results

Only one of the 8 rabbits (12.5%) having received cornstarch-thickened water survived until day 4. In contrasts, all the animal treated with water (n = 8) or xanthan-gum-thickened water (n = 8) survived. Aspiration of cornstarch-thickened was associated with a small but significant increase in intra-alveolar hemorrhage in the cornstarch group, relative to the two other groups. Relative to water alone, xanthan-gum-thickened water was associated with greater pulmonary inflammation, pulmonary interstitial congestion, and alveolar edema.

• Conclusion

In the rabbit, aspiration of cornstarch-thickened water for three consecutive days was fatal. Aspiration of xanthan-gum-thickened water was not fatal but damaged the lung, relative to water alone.

Study Summary

Novel non-invasive dysphagia detection system (DDS) for bedside assessment of swallowing in patients at risk of oropharyngeal dysphagia: results from an exploratory study

Steele CM, Mukherjee R, Muehlemann N, Jedwab M, Bath PM, Lees KR, Meretoja A, for the SONAR Investigators

Congress Abstract (AS03-046) - European Stroke Organisation Conference (ESOC) 2017 - Prague

http://journals.sagepub.com/toc/esoa/2/1_suppl

• Background

Post-stroke dysphagia is associated with elevated mortality and morbidity. The early identification of dysphagia is critical for optimizing outcomes in stroke patients. However, the performance levels of the available dysphagia screening tools vary.

• Methods

In a prospective, multicenter study, a newly developed, accelerometry-based dysphagia detection system (DDS) was compared with simultaneous videofluoroscopy. A mixed population of patients swallowed barium solutions with thin, moderately thick or extremely thick consistencies. The DDS's ability to detect dysphagia was assessed as the area under the receiver operating characteristic curve vs. videofluoroscopy.

• Results

332 patients were included, of whom 107 (32%) were stroke patients. A total of 4229 boluses were analyzed. According to the videofluoroscopy assessment, dysphagia affected 23% of the patients and 7.2% of the boluses. Hence, not all swallows were affected for a given patient. The prevalence of dysphagia decreased as the consistency of the barium solutions increased. With thin, moderately thick and extremely thick consistencies, the prevalence of dysphagia among the patients was 13.9%, 5.0% and 3.7%, respectively. In a per-bolus analysis, the prevalence of dysphagia with these consistencies was respectively 5.8%, 2.0% and 1.4%. Four boluses were found to be a practical number of tries to detect a problem. For the DDS, the area (standard deviation) under the receiver operating characteristic curve was 0.82 (0.06), the sensitivity was 86.7% (8.8), and the specificity was 60.4% (4.9).

• Conclusion

The accelerometry-based DDS achieved its target level of performance in detecting dysphagia with slightly thick swallowed preparations.

Study Summary

Budget impact of post-stroke dysphagia: database analyses of hospital discharges in France and Switzerland

Muehlemann N, Saitta B, Jouaneton B, de Léotoing L, Arnold M, Kaegi G

Congress Abstract (AS10-039) - European Stroke Organisation Conference (ESOC) 2017 - Prague

http://journals.sagepub.com/toc/esoa/2/1_suppl

• Background

Post-stroke dysphagia is associated with elevated mortality, morbidity, and healthcare system costs.

• Methods

In order to evaluate the impact of dysphagia on the length of hospital stay (LOS) and costs (from a hospital perspective), the investigators analyzed French and Swiss national hospital discharge databases (PMSI and OFS, respectively) by comparing hospital stays by stroke patients with vs. without dysphagia (as identified by diagnostic and procedure codes).

• Results

In Switzerland, dysphagia was recorded in 8.4% of hospital stays by stroke patients. In France, the proportion was 4.2%. The investigators suggested that this disparity might be due to differences in coding. In France, the LOS was longer for stroke patients with dysphagia (23.7 days) than for stroke patients without dysphagia (11.8 days). The same was true in Switzerland: 14.9 days for stroke patients with dysphagia vs. 8.9 days for those without dysphagia. The estimated cost increase associated with post-stroke dysphagia was 3000 euros in France and 14000 Swiss francs in Switzerland.

• Conclusion

In both France and Switzerland, post-stroke dysphagia is associated with a longer LOS and higher hospital costs.

Study Summary

Effect of structured physical activity and nutritional supplementation on physical function in mobility- limited older adults: Results from the VIVE2 randomized trial

Fielding RA, Travison TG, Kirn DR, Koochek A, Reid A, Von Berens Å, Zhu H, Folta SC, Sacheck JM, Nelson ME, Liu CK, Åberg AC, Nydahl M, Lilja M, Gustafsson T, Cederholm T

J Nutr Health Aging. 2017;21(9):936-942

https://www.ncbi.nlm.nih.gov/pubmed/29083433

• Background

Although nutritional supplementation and physical activity both have impacts on physical function, the interaction between the two factors has not been fully characterized.

• Methods

In a two-center study in Boston (USA) and Stockholm (Sweden), the impact of nutritional supplementation (or placebo supplementation) and a structured physical activity program (walking, strength, balance, and flexibility exercises, with three sessions a week for 24 weeks) was assessed (as gait speed in the 400m walk) in a population of older adults with limited mobility and vitamin D insufficiency recruited from urban communities. The intervention was a nutritional supplement (150 kcal, 20 g whey protein, 800 IU vitamin D) and the placebo was a 30 kcal non-nutritive supplement).

• Results

A total of 149 older adults were included (mean ± standard deviation age: 77.5±5.4; females: 46.3%; mean serum 25(OH)D level: 18.7±6.4 ng/ml; mean baseline Short Physical Performance Battery score: 7.9±1.2). The intervention and control (placebo supplement) groups displayed similar levels of adherence, both for the supplementation program (86% and 88%, respectively) and the physical activity program (75% and 72%, respectively). Although gait speed in the 400m walk increased in the intervention and control groups (by 0.071 and 0.108 m/s, respectively; p=0.06), the intergroup difference was not statistically significant. Administration of the nutritional supplement increased serum 25(OH)D levels (to 7.4 ng/ml, vs. 1.3 ng/ml in the placebo group).

• Conclusion

Both groups increased gaits speed in the 400m walk test, although not statistically significant. A significant increase in serum 25(OH) D levels was observed in the intervention group respect to placebo.

Study Summary

Older people's experiences from a health promoting intervention combining exercise and nutrition – a qualitative study by focus group interviews

Von Berens Å , Nydahl M, Koochek A, Cederholm T, Gustafsson T, Kirn DR, Reid KF, Fielding RA, Södergren M

Congress Abstract - ICFSR 2017 - Barcelona
ICFSR Congress/Journal of Frailty and Aging Volume 6, Supplement 1, 2017, page 102
https://frailty-sarcopenia.com/docs/abstracts-2017.pdf

• Background

As the population in some countries ages, the age-related loss of skeletal muscle mass and strength impacts personal independence and well-being. Regular exercise and nutrition have roles in countering sarcopenia.

• Methods

The objective of this qualitative, interview-based study (part of the VIVE2 multicenter, randomized clinical trial in Sweden) was to assess factors associated with adherence to exercise and nutrition programs in older adults (>70 years of age) with some limitations in mobility. The participants were all involved in a 6-month exercise program 2-3 days per week and receiving a nutritional supplement or placebo. Focus group interviews (in four sessions) were conducted with a subgroup of participants from the VIVE2 trial.

• Results

8 women and 12 men (mean (range) age = 77.5 (71-86)) participated in the study. A manifest and latent content analysis was based on Graneheim and Lundman's concepts of credibility, dependability and transferability. The main reasons for participating in the intervention were concerns about the negative effects of a sedentary life-style, a desire to lose weight, and difficulties in performing regular exercise and nutritional interventions alone. Participation was associated with greater self-confidence, enjoyment and safety. Group support was a major motivating factor for participation, and most of the participants wished to continue the activities after the end of the program.

• Conclusion

Physical and mental effects were related to the intervention. Group support and fear of non-compliance if performing actions alone were key motivators in a lifestyle intervention to counter sarcopenia and possible loss of independence in older adults on Sweden.

Study Summary

Physical performance and serum - 25(OH)vitamin D status - in community dwelling old mobility limited adults: - a cross-sectional study

Von Berens Å, Cederholm T, Fielding RA, Gustafsson T, Kirn DR, Laussen J, Nydahl M, Travison TG, Reid K, Koochek A

J Nutr Health Aging. 2018;22(1):1-7

https://link.springer.com/article/10.1007%2Fs12603-016-0849-0

• Background

The relationship between vitamin D status and physical performance in older adults remains to be fully characterized.

• Methods

In a two-center, cross-sectional study performed in the USA and Sweden, community-dwelling older adults with limited mobility (i.e. Short Physical Performance Battery score ≤ 9) participated in a combined physical exercise and nutrition intervention program. Logistic and linear regression analyses were used to assess a putative association between vitamin D status (marker: serum 25(OH)D level) and the physical performance (overall score for the Short Physical Performance Battery, chair stand performance, gait speed, and balance).

• Results

A total of 610 community-dwelling, mobility-limited older adults (USA center: n=494; Swedish center: n=116) were recruited (mean age 77.6 ± 5.3 years; females: 59%). The only significant relationship with serum 25(OH)D (cut-off: >74 nmol/L) was the time in seconds needed to perform a chair stand.

• Conclusion

There were no clear associations between serum 25(OH)D levels and physical performance in mobility-limited older adults in two centers from the USA and Sweden. However, better performance in a chair stand test was associated with higher serum 25(OH)D levels (>74 nmol/L).

Study Summary

Nutritional supplementation with physical activity improves muscle composition in mobility-limited older adults, the VIVE2 study: a randomized, double-blind, placebo-controlled trial

Englund DA, Kirn DR, Koochek A, Zhu H, Travison TG, Reid KF, von Berens Å, Melin M, Cederholm T, Gustafsson T, Fielding RA

J Gerontol A Biol Sci Med Sci. 2017 Dec 12;73(1):95-101

https://www.ncbi.nlm.nih.gov/pubmed/28977347

• Background

In older adults, muscle strength and mass can be increased by physical activity and dietary supplementation. However, the two factors' long-term effectiveness has yet to be proven.

• Methods

Older adults with vitamin D insufficiency (serum 25(OH)D ranging from 9 24 ng/mL) and limited mobility (Short Physical Performance Battery score ≤9) were included in a 6-month physical activity program. The participants were randomized to receive either a nutritional beverage (150 kcal, 20 g whey protein, and 800 IU vitamin D in 119 mL) or a similar but nonnutritive placebo during the program. Before and after the dietary and physical activity intervention, the investigators assessed muscle strength, power and quality, the total-body composition (using dual energy X-ray absorptiometry) and thigh composition (using CT).

• Results

A total of 149 older adults [mean ± SD age: 78.5 ± 5.4; 46.3% female] were randomized into the study. In both groups, muscle strength, body composition, and thigh composition improved over the course of the physical activity program. The dietary intervention was associated with significant additional improvements with regard to the loss of intermuscular fat (p=0.049) and greater muscle density (p= 0.018).

• Conclusion

In mobility-limited older adults undergoing a 6-month physical activity program, nutritional supplementation leads to greater benefits (with regard to muscle performance and body/tissue composition) than placebo.

Study Summary

Development of the nutrition and functionality assessment (NFA) among older adults in Japan

Okubo Y, Nemoto M, Osuka Y, Jung S, Seino S, Figueroa R, Vinyes-Pares G, Offord EA, Shevlyakova M, Breuille D, Tanaka K

The Journal of Frailty and Aging (JFA). http://dx.doi.org/10.14283/jfa.2017.38

http://www.jfrailtyaging.com/all-issues.html?article=607

• Background

There is a need for reliable tools that screen older adults for nutritional status and physical function, so that eligible individuals can benefit from personalized nutrition and exercise programs.

• Methods

In a cross-sectional study of community and geriatric day-care centers in Japan, the researchers developed and evaluated the Nutrition and Functionality Assessment (NFA) tool. Nutrition (using the protein intake and the short form of the Mini Nutrition Assessment), physical strength (hand-grip strength and 30s chair sit-to-stand), physical endurance (6-minute walk test), and physical activity (use of an accelerometer for a week) were assessed. The main inclusion criterion was a gait speed between 0.6 and 1.5 m/s.

• Results

A total of 267 adults aged 65 to 90 were enrolled, and 185 met the gait speed criterion. Of these, 184 (95%) completed the assessments. The NFA's physical functionality and overall scores (but not the nutrition score) were significantly related to a frail phenotype. No adverse events linked to NFA implementation were reported.

• Conclusion

The NFA is a safe, feasible tool for simultaneously screening for nutritional status and physical function in older adults in Japan. The NFA's validity was demonstrated but only in part.

Study Summary

Evaluation of the effectiveness of a rich supplement in fiber and sorbitol on the constipation of elderly persons who live in residential centers

Sobrón I, Imaz C, Lacarra E, Barbosa A, López B, Pérez V, Barcons N

Rev Esp Nutr Hum Diet. 2017; 21(2): 164-173
http://renhyd.org/index.php/renhyd/article/view/355

• Background

Constipation is frequent in elderly adults in residential care. Nutritional supplementation can reduce the need for laxative medications.

• Methods

In a prospective, interventional, single-center study in a nursing home, elderly residents with previous constipation and laxative treatment received nutritional supplementation with a fiber- and sorbitol-rich dessert for 7 weeks. Laxative use (quantity, and the number of days with laxative treatment) was assessed during the week immediately prior to initiation and then during the last week of the supplementation period.

• Results

A total of 40 patients (median (range) age: 88.5 (72-101)) were included in the study. Compliance with the supplementation regimen was high (>94%). Bowel movements increased by an average of 2 per week. Laxative use was lower at the end of the intervention (40% less in quantity, and 3.5 fewer days with laxative treatment per week). This decrease in days with laxative treatment was associated with the following factors: high compliance, age over 85, poor oral health, and the absence of malnutrition or food disorders.

• Conclusions

In a pre-/post- study, 7 weeks of nutritional supplementation with a fiber- and sorbitol-rich dessert reduced constipation and laxative medication use in elderly nursing home residents.

Study Summary

Achieving Protein Targets in the ICU with a Specialized Enteral Formula

Hopkins B, Alberda C

Can J Diet Pract Res. 2016 Sep;77(3):e1-e14

https://www.ncbi.nlm.nih.gov/pubmed/27524632

• Background

According to the latest guidelines, critically ill patients (e.g. those admitted to the ICU) should receive higher amounts of protein - up to 2-2.5 g protein/kg/day, compared with measured values < 0.7 g/kg/day in the literature. The provision of this protein requirement may reduce morbidity and mortality. High-protein enteral nutrition formulas constitute one possible strategy for delivering the extra protein.

• Methods

In this Canadian study performed in six ICUs, participants receiving an enteral nutrition formula in which protein accounts for 37% of the calories were assessed with regard to protein and energy targets, BMI, the reason for initiating the enteral nutrition formula and (for the first 5 days of feeding) the protein and energy delivered, feeding interruptions and general tolerance.

• Results

A total of 49 patients were included in the study, and 44 had two or more days of exploitable data. The rationale for initiating enteral nutrition formula was variously obesity, the use of lipid-based medications, the protein/calorie ratio, high protein needs, and renal replacement therapy. The mean protein intake (112 g/day, 1.6 g/kg bodyweight) was somewhat lower than the mean prescribed intake (134 g/day, 1.9 g/kg) but was well over the value of 0.7 g/kg/day. The same was true for the delivered and prescribed energy intake (1338 kcal/day vs. 1626 kcal/day, respectively). Thirty-eight of the 44 patients (86%) were free of gastrointestinal tract symptoms.

• Conclusion

In patients from six ICUs, a specialized enteral nutrition formula was well tolerated and enabled the delivery of greater amounts of protein by these critically ill individuals.

Study Summary

Use of a Very High Protein Enteral Nutrition Formula Assists in Meeting the Protein Needs of Patients Receiving Intravenous Sedation with Propofol

Wieser J, Cohen S, Ochoa Gautier JB, Huhmann M

Congress Abstract - ASPEN Clinical Nutrition Week 2017 - Orlando

http://journals.sagepub.com/doi/suppl/10.1177/0148607116686023/suppl_file/CNW17_Monday_Posters_final.pdf

• Background

In critically ill patients, marked muscle proteolysis increases protein requirements. Propofol, often used to manage critically ill patients is administered in a lipid vehicle, which increases the calorie intake. To avoid calorie overload, enteral nutrition (EN) support must be adjusted using protein formulas.

• Methods

This study of critically ill adult patients receiving propofol in the intensive care unit assessed protein intake before and after the market introduction of a very-high-protein (VHP) EN formula (i.e. versus a standard (STN) protein formula). Data on age, gender, diagnosis on admission, propofol dose, nutritional requirements, and mean calorie and protein intakes were gathered from medical records.

• Results

A total of 40 adult critically ill patients with neurologic diagnoses on admission participated in the study (males: 68%; mean age: 38.3). The VHP and STN groups (n=20 patients in each) did not differ significantly with regard to the daily calorie intake provided by propofol (516.6 and 492.0 kcal/day, respectively). The daily protein intake was significantly higher in the VHP group (97.9 ± 28.6 g/day) than in the STN group (81.7 ±19.5 g/day; p=0.044), and the daily total caloric intake was lower (albeit not significantly) in the VHP group (1593.7 ± 393 kcal/day) than in the STN group (1825.2 ± 398.1 kcal/d; p=0.072).

• Conclusion

A VHP EN formula increased protein intake without increasing caloric intake in critically ill adults receiving propofol in the intensive care unit, which may enable better compliance with nutrient provision guidelines.

Study Summary

Availability of a Very High Protein Enteral Nutrition Formula Leads to Change in Practice in Nutrition Prescription

Wieser J, Cohen SS, Ochoa Gautier JB, Huhmann M

Congress Abstract - ASPEN Clinical Nutrition Week 2017 - Orlando

http://journals.sagepub.com/doi/suppl/10.1177/0148607116686023/suppl_file/CNW17_Monday_Posters_final.pdf

• Background

In critically ill patients, marked muscle proteolysis increases protein requirements. Enteral nutrition (EN) support for these patients is based on high-protein formulas. Administration of additional protein supplements is associated with an increased use of nursing resources.

• Methods

This retrospective chart review was part of a larger study of critically ill adult patients with neurological diagnoses and sedated with propofol in the intensive care unit, performed before and after the market introduction of a very-high-protein (VHP) EN formula (i.e. versus a standard (STN) protein formula). The substudy's primary objective was to calculate the energy and protein needs of these patients. For five days of EN, data on estimated nutritional needs and enteral prescriptions were gathered.

• Results

A total of 40 adult critically ill patients participated in the study (males: 68%; mean age: 38.3). The VHP and STN groups comprised 20 patients each. The mean estimated protein needs were 12-16 g/day lower in the STN group than in the VHP group. The mean estimated caloric needs were 146-157 Kcal/day higher in the STN group than in the VHP group. The difference was statistically significant for the upper end of the estimated protein needs.

• Conclusion

The introduction of the VHP EN formula changed practice with regard to the estimated protein and caloric needs; the estimated protein needs increased and the estimated caloric needs decreased (albeit not in a statistically significant way for all parameters).

Article Summary

Summary Points and Consensus Recommendations from the International Protein Summit

Hurt RT, McClave SA, Martindale RG, Ochoa Gautier JB, Coss-Bu JA, Dickerson RN, Heyland DK, Hoffer LJ, Moore FA, Morris CR, Paddon-Jones D, Patel JJ, Phillips SM, Rugeles SJ, Sarav Md M, Weijs PJ, Wernerman J, Hamilton-Reeves J, McClain CJ, Taylor B

Recommendations: Nutr Clin Pract. 2017 Apr;32(1_suppl):142S-151S
https://www.ncbi.nlm.nih.gov/pubmed/28388374

• Background

In the ICU, high doses of protein (range: 1.2–2.5 g/kg/d) may optimize nutrition and reduce mortality.

• Methods

In order to provide recommendations to healthcare professionals in their clinical practice and define topics for future research, the International Protein Summit in 2016 brought together experts in clinical nutrition and protein metabolism. They assessed the literature on the impact of high-dose protein diets on clinical outcomes and on obstacles to protein delivery in the critically ill patient.

• Results

Protein doses in the range 1.2–2.5 g/kg/d are not able to reverse the catabolic response but may be require for new protein synthesis and the maintenance of muscle mass. The protein's source, amino-acid content, and digestibility all affect the body's nutrient-sensing pathways. In the first week after admission to the ICU, protein targets are more important than energy targets (meeting 80%–90% of energy requirements is acceptable).

• Conclusion

A high-protein, moderately hypocaloric diet may turn out to be the best strategy after admission to the ICU (better maintenance of protein homeostasis and greater insulin sensitivity).

Article Summary

How Much and What Type of Protein Should a Critically Ill Patient Receive?

Ochoa Gautier JB, Martindale RG, Rugeles SJ, Hurt RT, Taylor B, Heyland DK, McClave SA

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl):6S-14S

https://www.ncbi.nlm.nih.gov/pubmed/28388376

• Background

Significant alterations in protein metabolism are observed in almost all critically ill patients: 30% or more have significant protein malnutrition.

• Methods

A literature review/opinion article.

• Results

From a historical perspective, advances in nutrition science concerning protein malnutrition were prompted by the establishment of modern prison systems in the 19th century and during war and famines in the 20th century. In the 1960s, it was suggested that "hyperalimentation" (with the provision of calories in excess of metabolic needs) was beneficial in critically ill patients. In contrast, modern observational studies suggest that meeting only 80% of the caloric goal is nevertheless associated with the best clinical outcomes, and that meeting protein goals has a greater impact on decreasing mortality. The protein requirement in a healthy adult is 0.6–0.8 g/kg/d. Experts have recommended at least 1.2 g protein/kg/d (and even up to 2.0-2.5 g protein/kg/d) in critically ill patients. The amino acid composition is also a factor that should match the metabolic requirement. Given that arginine deficiency is known to impair T lymphocyte function in trauma after surgery, arginine-based immunonutrition may restore arginine levels in the amino acid pool for surgical or trauma patients. Arginine-based immunonutrition is associated with a significantly lower risk of postsurgical infection.

• Conclusion

Improved protein delivery is associated with better clinical outcomes. Patients with specific amino acid deficiencies and nutrition requirements may require specific (immuno)nutrition formulations.

Article Summary

Assessment of Protein Turnover in Health and Disease

Wernerman J, Morris CR, Paddon-Jones D, Sarav M

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl):6S-14S

https://www.ncbi.nlm.nih.gov/pubmed/28388376

• Background

Estimation of protein requirements in health and in illness (e.g. critically ill patients) requires an understanding of basic physiology, practical measurement methods, and the protein dose-response curve.

• Methods

A literature review/opinion article.

• Results

Dietary proteins are primarily digested in the upper GI tract, with the uptake of oligopeptides and single amino acids. First-pass elimination (due to passage through enterocytes and hepatocytes) must be taken into account when analyzing the effect of protein in enteral nutrition. There are marked differences in first-pass elimination between healthy individuals and critically ill patients. Enteral uptake and protein turnover are measured with appropriate tracer techniques. For example, amino acid oxidation may be estimated by using a 13C-labeled tracer and measuring the 13C-CO2 in expired air. The utilization of dietary protein is usually assessed by measuring the nitrogen balance. The protein dose-response relationship is linear (using the net amino acid tracer balance) at normal levels of protein intake (0.5–1.5 g/kg/d in healthy individuals) but may not be at the very high levels (2–3 g/kg/d) given to critically ill patients. Furthermore, knowledge of organ-specific protein turnover is needed for interpreting whole-body measurements.

• Conclusion

All techniques for measuring the protein dose-response have one or more inherent limitations. Data can be over-interpreted. Given the absence of consensus in healthy individuals, it is not surprising that the findings are even more controversial in critically ill patients.

Article Summary

Protein Kinetics and Metabolic Effects Related to Disease States in the ICU

Martindale RG, Heyland DK, Rugeles SJ, Wernerman J, Weijs PJ, Patel JJ, McClave SA

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl):21S-29S

https://www.ncbi.nlm.nih.gov/pubmed/28388373

• Background

To date, heterogeneity in the studied populations of critically ill patients makes it difficult to make firm recommendations on an individual's protein kinetics and needs in the ICU.

• Methods

A literature review/opinion article.

• Results

In the ICU, patient immobilization, a general catabolic state, a decrease in muscle protein synthesis, an increase in muscle degradation, and an increase in apoptosis lead to massive muscle protein. Amino acid (AA) transport is affected in the liver, kidney, brain, and muscles. It has been reported that core muscle groups (including the diaphragm) lose volume faster than peripheral muscles do. Age, sex, body size, nutrition administration route and even the microbiome appear to influence total-body protein kinetics. The presence of sepsis complicates protein kinetics. Although 1.2 to 2 g/kg/d protein is recommended in the ICU, the actual amount delivered is often closer to 0.5 g/kg/d. However, recent studies of AA oxidation methods based on stable isotopes (13C) have shown that high-level protein delivery in the ICU patient is safe – as long as adequate energy sources from carbohydrate are also delivered. Amino acids such as leucine and branched-chain AAs stimulate total-body protein synthesis. Better knowledge of the regulation of protein and AA metabolism by mTOR is opening up new perspectives for studying AA and protein kinetics in the critically ill patient. Protein supplementation and early mobilization have consistently demonstrated positive effects, although the results of protein supplementation alone are less clear.

• Conclusion

There are few high-quality studies of protein kinetics in the ICU. However, the literature data suggest that critically ill patients can use protein or AAs delivered at high levels (at least 2.0 g/kg/d and possibly higher).

Article Summary

Acquired Amino Acid Deficiencies: A Focus on Arginine and Glutamine

Morris CR, Hamilton-Reeves J, Martindale RG, Sarav M, Ochoa Gautier JB

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl):30S-47S

https://www.ncbi.nlm.nih.gov/pubmed/28388380

• Background

In healthy individuals, glutamine and arginine are usually classified as nonessential amino acids. However, clinically important glutamine and arginine deficiencies occur in certain illnesses and require dietary supplementation.

• Methods

A literature review/opinion article.

• Results

Arginine synthesis is performed by the small intestine and kidneys. Damage to either organ can compromise arginine bioavailability. Arginase is released after inflammatory signaling and cell damage (notably hemolysis), reducing arginine levels. Plasma arginine levels fall within minutes of trauma and may remain low for weeks. Low bioavailability of L-arginine (the sole precursor for nitric oxide (NO) compromises NO bioavailability and result in endothelial dysfunction in lung injury, fibrosis, and pulmonary hypertension. Arginine is essential for the proliferation and maturation of human T cells and for M1 to M2 macrophage transition; depletion induces T-cell dysfunction and increase susceptibility to infection. Arginine deficiency is also implicated in malaria, thalassemia, sepsis and poor recovery from surgery. Patients with malabsorption, celiac disease, cystic fibrosis, preeclampsia or sepsis may also benefit from arginine supplementation. The normal intake of 2–7 g/d L-arginine can be raised to 6–30 g/d L-arginine. Glutamine contributes to normal intestinal barrier function and can become deficient in Crohn's disease, diarrheal illness, and short gut syndrome, sickle cell disease, β-thalassemia, malaria, trauma, burns, and low birthweight infants. Orally or parenteral glutamine has been studied in many clinical scenarios.

• Conclusion

Arginine and glutamine-based immunonutrition is an emerging approach but subsets of responders have yet to be fully defined.

Article Summary

Variation in Protein Origin and Utilization: Research and Clinical Application

Paddon-Jones D, Coss-Bu JA, Morris CR, Phillips SM, Wernerman J

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl):48S-57S

https://www.ncbi.nlm.nih.gov/pubmed/28388379

• Background

Even brief periods of hospitalization are associated with loss of skeletal muscle and strength, and anabolic resistance.

• Methods

A literature review/opinion article.

• Results

The essential branched-chain amino acids (BCAAs: leucine, isoleucine, and valine) are protein building blocks but also serve as signaling molecules. In the elderly and in patients with a BCAA deficiency, meal supplementation with just 3–4 g of leucine per meal may trigger the muscle protein synthesis. The quantity of protein recommended in critically ill patients ranges from 1.2–2.5 g/kg/d. The RDA (0.8 g/kg/d) is often misinterpreted; it is estimate of the minimum (and not optimal) requirement and applies to healthy (not critically ill) populations. The composition and thus digestibility of protein is at least as important as the quantity. In 2013, the Food and Agriculture Organization introduced the Digestible Indispensable Amino Acid Score. This score compares the ratio of essential amino acids in the tested protein to those in a reference protein while correcting for ileal digestibility. Although technically imperfect, the DIAAS has been broadly accepted by researchers. In patients, supplementation with preparations of dairy-based protein (mainly whey and casein) and some soy preparations or blends are currently favored. Incomplete protein supplement are unlikely to resolve muscle breakdown. When protein supplementation is delivered as a bolus, 20-35 g of protein stimulates skeletal muscle protein synthesis.

• Conclusion

Future clinical trials to optimize protein supplementation should be based on mechanistic hypotheses obtained in cell-, animal-, and/or patient-based settings.

Article Summary

Protein Delivery in the Intensive Care Unit: Optimal or Suboptimal?

Heyland DK, Weijs PJ, Coss-Bu JA, Taylor B, Kristof AS, O'Keefe GE, Martindale RG

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl):58S-71S

https://www.ncbi.nlm.nih.gov/pubmed/28388372

• Background

Protein/amino acid supplementation (up to 2.0–2.5 g/kg/d) is likely to improve the recovery of critically ill patients.

• Methods

A literature review/opinion article.

• Results

In a 2014 survey of clinical practice in 187 ICUs (4000 patients) worldwide, the mean prescribed protein dose was too low (1.3 g/kg/d; interquartile range [1.0–1.5 g/kg/d]; range, 0.5–3.8 g/ kg/d). Furthermore, actual protein delivery (mainly from enteral nutrition (EN) formulas) was lower still. However, it has been shown that an additional 30 g protein/d or 1000 calories/d improves outcomes in critically ill patients. The impact of nutritional interventions on muscle and patient performance can be estimated by the patient' muscle structure and function, activity limitations, participation restriction, and quality of life. However, large clinical trials may fail to demonstrate the impact of nutrition because of the heterogeneity of the study populations (the inclusion of non-responders). High-protein enteral solutions (35%–37% protein, 88–92 g/L) are now commercially available and may enable greater protein intake. Parenteral sources of protein/amino acids are also readily available but are underused. The targets for enteral nutrition are now 1.2–1.5 g/kg in non-critical patients and 1.5–2 g/kg in burns, surgical and trauma patients. Repeated, standardized measurements of muscle dimension at the bedside may be a marker of outcomes.

• Conclusion

Critically ill patients are still receiving suboptimal amounts of protein/amino acids – despite the commercially availability of appropriate high-protein enteral solutions, protein supplements, and parenteral amino acid–containing solutions). By not providing optimal protein/amino acids, patient's care may be suboptimal.

Article Summary

How Many Nonprotein Calories Does a Critically Ill Patient Require? A Case for Hypocaloric Nutrition in the Critically Ill Patient

Rugeles SJ, Ochoa Gautier JB, Dickerson RN, Coss-Bu JA, Wernerman J, Paddon-Jones D

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl):72S-76S

https://www.ncbi.nlm.nih.gov/pubmed/28388377

• Background

Critically ill patients display high protein catabolism and variable levels of glucose and fatty acid oxidization. Hyperglycemia is a major problem. The match between needs and supply is difficult, and there is no easy method for calculating the calorie requirement of a given critically ill patient.

• Methods

A literature review/opinion article.

• Results

The expert consensus target for caloric needs is 25–30 kcal/kg/d. However, it can be hypothesized that poor outcomes in acutely or critically ill patients are due to a protein debt rather than a caloric debt. Rugeles et al. looked at whether hypocaloric, high-protein nutrition (15 kcal/kg/d and 1.5 g protein/kg/d) might improve clinical and metabolic outcomes in critically ill patients, relative to a 25 kcal/kg/d formula with 20% of the calories as protein. They indeed found a benefit, according to the improvement at 48 hours in the Sequential Organ Failure Assessment score. In a second trial in the ICU, Rugeles et al. compared hypocaloric (12 kcal/kg/d), hyperproteic (1.4 g/kg/d) nutrition with normocaloric (19.2 kcal/kg/d), hyperproteic (1.4 g/kg/d) nutrition in the ICU setting. There were significant differences in hyperglycemic events, the requirement for insulin, and the total insulin dose but not in the clinical outcomes.

• Conclusion

During the first week in the ICU, hyperproteic (1.4 - 2.0 g/kg/d), hypocaloric nutrition (15 kcal/kg/d) is a physiological strategy for controlling hyperglycemia. A normocaloric approach can be applied thereafter.

Article Summary

Experimental and Outcome Based Approaches to Protein Requirements in the Intensive Care Unit

Weijs PJ, Dickerson RN, Heyland DK, Moore FA, Rugeles SJ, McClave SA

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl):77S-85S

https://www.ncbi.nlm.nih.gov/pubmed/28388371

• Background

Critical illness is associated with major protein loss, which may be alleviated by protein supplementation.

• Methods

A literature review/opinion article.

• Results

A small, nonrandomized 1987 tracer study in 18 severely septic patients found that net protein breakdown was lowest at 1.24 g protein/kg. A 1990 nitrogen balance study of burns/trauma patients found that protein loss could be optimally reduced by 1.25–1.56 g/kg. In a 1998 study of 18 trauma and 5 sepsis patients, body protein loss measurements favored 1.2 g/kg preadmission body weight. A 2015 nitrogen balance study of 194 trauma patients indicated a required intake above 1.0–1.5 g/kg. A 2015 protein turnover tracer in 13 critically ill patients found a linear relationship between protein/amino acid intake and protein balance. The outcome-based approach involves hard indicators like 28-day ICU mortality and hospital mortality, which may be dose-dependent with lowest mortality in patients receiving >1.2 g protein/kg. When patients meet targets for energy, higher levels of protein are associated with a better outcome. There is some agreement that trauma patients require >1.5 g/kg and sepsis patients require >1.2 g/kg. The NUTRIC score and CT scans of muscle mass are possible approaches to personalization of protein supply.

• Conclusion

Experimental and outcome-based studies indicate a protein requirement of >1.2 g protein/kg. A higher level of personalization is required.

Article Summary

Protein and Calorie Requirements Associated with the Presence of Obesity

Dickerson RN, Patel JJ, McClain CJ

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl):86S-93S

https://www.ncbi.nlm.nih.gov/pubmed/28388369

• Background

In many western societies, over a quarter of patients in the ICU patients are obese. These patients may require a specific nutrient program.

• Methods

A literature review/opinion article.

• Results

Protein turnover, catabolism, hypertriglyceridemia and insulin resistance are greater in obesity. Inadequate nutrition for ICU patients with obesity leads to worse wound healing, functional status and survival. The use of hypocaloric, high-protein nutrition therapy in obese patients is designed to preserve lean body mass, mobilize adipose stores, and minimize the potential complications of hypercaloric diets. The authors reviewed 6 comparative studies and 2 case series totaling 226 obese patients receiving hypocaloric, high-protein nutrition support therapy. The mean protein intakes ranged from 1.5 to 2.2 g/kg ideal body weight and caloric intakes ranging from 18–25 kcal/kg IBW/d. The clinical outcomes of hypocaloric feeding were at least as good as or even better than eucaloric diets. Patients with class III obesity, older patients, and patients with renal failure may require further adjustment. For example, class III obesity required ~2.5 g/kg IBW/d for nitrogen balance (the most practical marker), whereas class I or II required ~2 g/kg IBW/d. The risk of higher protein intake in older patients is azotemia, which should be monitored for via the serum urea nitrogen concentration, uremia, and worsened encephalopathy.

• Conclusion

The recommended protein intake is 2 g/kg IBW/d in patients with a BMI 30–39.9 kg/m^2 and 2.5 g/kg IBW/d in patients with a BMI ≥40 kg/m^2.

Article Summary

Will We Ever Agree on Protein Requirements in the ICU?

Hoffer LJ, Dickerson RN, Martindale RG, McClave SA, Ochoa Gautier JB

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl):94S-100S

https://www.ncbi.nlm.nih.gov/pubmed/28388370

• Background

The protein requirements of critically ill patients have never been precisely defined. Most current recommendations are based on biomarker studies, rather than clinical endpoints.

• Methods

A literature review/opinion article.

• Results

The key question is how much protein should be provided to which patients, and when during their critical illness. Despite cost issues and heterogeneity in patient status, prospective randomized clinical trials (RCTs) with hard clinical endpoints and metabolic outcomes can be performed in the intensive care unit (ICU). Critical illness results in whole-body loss of nitrogen but the only published study in this field did not find an association between severity scores and the rate of body nitrogen loss in multiple trauma patients. Regarding muscle loss, it would be valuable to use ultrasound or CT to validate simple, clinical bedside procedures. The risk of calorie overfeeding and infections has unduly restricted the use of parenteral nutrition (PN), even though enteral nutrition (EN) also has limitations. Recently, a few small but well-designed RCTs have studied (i) hypocaloric, protein-deficient EN vs. hypocaloric high-protein EN, (ii) EN vs. EN+PN, and (iii) PN with 0.9 g/kg vs. 1.1 g/kg daily mixed amino acids. However, the results do not prove or disprove the putative increase in protein requirements in critical illness.

• Conclusion

Clinical indicators of nitrogen loss should be validated as a screen for patients with higher protein requirements. Muscle atrophy should be evaluated at the bedside. Hypocaloric high-protein EN requires further testing in high-quality RCTs.

Article Summary

Protein Requirements for Critically Ill Patients with Renal and Liver Failure

Patel JJ, McClain CJ, Sarav M, Hamilton-Reeves J, Hurt RT

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl): 101S-111S

https://www.ncbi.nlm.nih.gov/pubmed/28208022

• Background

Decompensated liver cirrhosis (DLC) and acute liver failure (ALF) often lead to ICU admission and are associated with proteolysis and amino acid loss. Furthermore, acute kidney injury (AKI) often develops in the ICU.

• Methods

A literature review/opinion article.

• Results

The 2016 US guidelines recommend 1.2–2.0 g/kg/d of protein in the ICU. More than half of ICU admissions have AKI on day 1 of admission in the ICU, which further worsens the clinical status. Furthermore, continuous renal replacement therapy of AKI exacerbates protein loss (10–15 g/d). In AKI, better safety and nitrogen balance have been noted with 1.5 to 2.5 g/kg/d protein. Early suggestions that parenteral supplementation with essential AAs (vs. standard AAs or hypertonic glucose) is beneficial in AKI have not been confirmed; some trials but not others have noted faster recovery and improved nitrogen balance. A large observational study of patients with alcoholic hepatitis found that positive nitrogen balance was only consistently achieved with >1.2 g/kg/d. Supplemental branched-chain AAs (BCAAs) may activate ammonia detoxification, mediate glucose metabolism and protein synthesis via the mTOR pathway, stimulate growth factor release, and improve neutrophil phagocytotic function but the clinical trial evidence is not conclusive. In DLC/ALF, the European and US guidelines respectively recommend 0.8–1.2 g/kg/d + BCAAs and 1.2–2.0 g/kg/d without BCAAs.

• Conclusion

High-protein enteral nutrition (EN) is indicated in AKI. BCAA supplementation is not unambiguously beneficial.

Article Summary

Protein Turnover and Metabolism in the Elderly Intensive Care Unit Patient

Phillips SM, Dickerson RN, Moore FA, Paddon-Jones D, Weijs PJ

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl): 112S-120S

https://www.ncbi.nlm.nih.gov/pubmed/28388378

• Background

Older patients admitted to the ICU are likely to be already suffering from muscle loss due to sarcopenia. This loss is markedly accentuated in the ICU. Care for older patients in and after the ICU is a key issue.

• Methods

A literature review/opinion article.

• Results

Sarcopenic muscle loss starts in the fifth decade of life and is accompanied with anabolic resistance. These processes are accentuated in older ICU patients. Although a protein supply of more than 0.8 g/kg/d is probably optimal for healthy older adults, the question of whether older ICU patients require more protein has not been definitively addressed in well-designed clinical trials. Likewise, the relative values and roles of enteral nutrition and parenteral nutrition have not been established. However, one trial concluded that older patients in the ICU were only able to achieve nitrogen equilibrium with protein intakes of 2–2.5 g/kg/d. In the ICU, physical therapy (sitting up, resistive work with elastic bands, neuromuscular electrical stimulation (NMES), and other forms of exercise in bed or if possible out of bed) is associated with better outcomes (greater muscle mass, better function, reduced need for ventilation, and shorter length of stay).

• Conclusion

In older ICU patients, the following should be explored in high-quality clinical trials: (i) early enteral and/or parenteral provision of (high-level) protein/amino acids, and (ii) physical therapy in the ICU and after discharge.

Study Summary

A randomized controlled pilot study to evaluate the effect of an enteral formulation designed to improve gastrointestinal tolerance in the critically ill patient – the SPIRIT trial

Jakob SM, Bütikofer L, Berger D, Coslovsky M, Takala J

Crit Care. 2017 Jun 10;21(1):140

https://www.ncbi.nlm.nih.gov/pubmed/28599662

• Background

Patients in intensive care units (ICU) frequently suffer from diarrhea, which may lead to complications, increase the nursing workload, and extend hospitalization.

• Methods

Adult patients in the ICU for five or more days and with tube feeding for three of more days were included in a pilot, single-center, double-blind, randomized controlled trial. Participants were randomized to an intervention enteral diet (Peptamen® AF) or a control enteral diet (Isosource® Energy). Diets were initiated within 72 hours of ICU admission and continued for up to 10 days. The investigators recorded the nutritional intake, the frequency of diarrhea, and the nursing workload up until 28 days post-randomization.

• Results

90 patients were included in the trial, with respectively 46 and 44 randomized to the interventional and control groups. There were no statistically significant intergroup differences with regard to calorie intake, time needed to achieve the caloric goal, time on the study diets, the incidence of diarrhea, use of fecal collectors, diarrhea-free days, nursing workload or the cost of diarrhea care. The median (interquartile range) protein intake was significantly higher in the interventional group (1.13 (0.78–1.31) g/kg/day) than in the control group (0.80 (0.70–0.94); $p<0.001$). After adjustment for treatment group, age, sex, and the SAPS II score, a post-hoc analysis showed that patients with diarrhea had a significantly more days on mechanical ventilation and a significantly longer stay on the ICU stay.

• Conclusion

Although patients randomized to the intervention enteral diet had significantly higher protein intake, there was no difference in the incidence of diarrhea and related outcomes between arms.

Article Summary

Clinical utility of partially hydrolyzed guar gum: review of evidence and experience

Canton A, Fernandez T, Lugo G, Martinez MA, Palmeiro R, Rita F, Tejera C

Review Article: Nutr Hosp. 2017;34:216-223

https://www.ncbi.nlm.nih.gov/labs/articles/28244794/

• Background

Dietary fibers have specific chemical, physical and physiological properties. Different diseases may require different types of dietary fibers, such as partially hydrolyzed guar gum (PHGG, a soluble, highly fermentable fiber with low viscosity).

• Methods

MEDLINE® was searched for publications on PHGG's physicochemical properties, possible mechanisms of action, and potential value in adult patients with various diseases.

• Results

The potential value of PHGG has been investigated in many clinical situations, including diabetes, hypercholesterolemia and bacterial overgrowth. The use of PHGG in patients with enteral-nutrition-associated diarrhea is supported by guidelines issued by learned societies in Europe and the USA. These promising results may be due to fermentative production of short-chain fatty acids in the colon.

• Conclusion

PHGG is of value in the treatment of enteral-nutrition-associated diarrhea. In other disease areas, better studies are required before guidelines can be issued.

Article Summary

A systematic scoping review on the clinical burden of hyperglycaemia in ICU patients

Danel A, Miret M, Olariu E, Pooley N, Preiser JC

Congress Poster - ASPEN Clinical Nutrition Week 2017 - Orlando

https://www.nestlenutrition-institute.org/resources/publication-series/publications/article/a-systematic-scoping-review-on-the-clinical-burden-of-hyperglycemia-in-icu-patients

• Background

Hyperglycemia frequently occurs in critically ill patients; almost 75% of intensive care unit (ICU) patients (including diabetics) have blood glucose >110 mg/dl.

• Methods

This was a systematic review of observational studies of hyperglycemia in adult ICU patients. The goal was to understand the clinical burden of hyperglycemia. Medline, Embase, and the Cochrane Library were searched from January 2000 to December 2015 for relevant publications.

• Results

A total of 4,388 records were retrieved, 385 full-text articles were reviewed, and 77 (covering 1,172,172 patients, ranging from 28 patients to 779,786 patients per study) were included in the review. Most had been performed in the USA (n=35) or Europe (n=22). The main blood glucose thresholds for hyperglycemia were variously 200 mg/dl (18 studies), 180 mg/dl (11 studies), 150 mg/dl (11 studies) and 140 mg/dl (9 studies), with a range from 100 to 300 mg/dl. Capillary (12 studies), arterial (11 studies) or venous blood glucose (8 studies) was measured with a variety of devices. Five out of eight relevant studies identified hyperglycemia as an independent risk factor for infections. Only one study looked at whether hyperglycemia was a risk factor for a prolonged ICU and hospital length of stay (it was).

• Conclusion

Although the methods and definition used in the literature are highly heterogeneous, hyperglycemia at admission or acquired in ICU is associated with elevated disease severity and a greater resource burden.

Study Summary

Hypocaloric High-Protein Enteral Nutrition Improves Glucose Management in Critically Ill Patients

Ochoa Gautier JB, Huhmann M, Files DC, Drover J, Bernard A, Ziegler T, Kress J, Ham KR, Grathwol D, Kulkarni H, Rice T

Congress Abstract - ASPEN Clinical Nutrition Week 2017 - Orlando

http://journals.sagepub.com/doi/full/10.1177/0148607116686023

• Background

In the USA, almost half of patients in the intensive care unit patients have hyperglycemia on or soon after admission. This condition is associated with increased morbidity, mortality and health resource use. Carbohydrate restriction may improve glucose control in these patients.

• Methods

In a group of seven university medical centers, this prospective, randomized, multicenter clinical study of mechanically ventilated critically ill, obese/overweight ICU patients requiring enteral nutrition (EN) compared blood glucose control (the number of glycemic events >150 mg/dL, between 81 and 110 mg/dL and <110 mg/dL) obtained with a hypocaloric, high-protein formulation (Peptamen® Intense VHP) or a normocaloric, high-protein formulation (Replete®). An interim analysis of 40 datasets (at least 5 days of data) was performed.

• Results

After 98 patients had been randomized, 40 had at least 5 days of data. The mean glucose level was significantly lower in the Peptamen® Intense VHP group (128 [114-143] than in the Replete® group (140 [125-158]; p=0.0443). Patients in the Peptamen® Intense VHP group had significantly fewer hyperglycemic episodes and a similar number of hypoglycemic episodes, relative to the Replete® group. The Peptamen® Intense VHP group received 12% fewer insulin administrations (p=0.044). There was no significant intergroup difference in the mortality rate.

• Conclusion

A hypocaloric hyperproteic diet, while not reducing variability, facilitates blood glucose management by decreasing episodes of hyperglycemia, decreasing insulin utilization, and normalizing blood glucose levels in adult ICU patients.

Study Summary

High protein, low carbohydrate, 100% whey based enteral formula is associated with lower blood glucose response

Huhmann MB, Neutel J, Cohen SS, Ochoa Gautier JB

Congress Abstract (MON-P239) - ESPEN 2017 - The Hague

http://www.clinicalnutritionjournal.com/article/S0261-5614(17)30850-6/fulltext

• Background

Hyperglycemia is prevalent among critically ill patients (notably those with type 2 diabetes) receiving enteral nutrition (EN). Dietary factors (such as protein content) may influence the prevalence of hyperglycemia in this setting.

• Methods

A crossover randomized clinical trial in 12 adults with type 2 diabetes sought to assess glycemic and insulin responses following the administration of 450 mL of an isocaloric amount of two high-protein EN formulas (a 100% whey based formula, Peptamen® Intense VHP, and a whey-casein-based formula, Vital® HP). Antidiabetic medication was prohibited during the experimental period. Blood glucose and insulin levels were measured up to 240 minutes post-administration.

• Results

Twelve adults participated on the study (5 males and 7 females, mean (range) age: 56 (40–66)). The mean area under the curve for glucose was significantly lower with Peptamen® Intense VHP than with Vital® HP (p=0.025). At the glucose peak (60 minutes post-administration), the difference from baseline was significantly lower in the VHP group (by 2.5 mmol/l; p=0.003). There were no intergroup differences in mean insulin levels.

• Conclusion

Relative to a whey-casein-based EN formula, a 100%-whey-based EN formula was associated with better blood glucose control and lower blood glucose levels in critically ill adult patients with type 2 diabetes.

Article Summary

Nutrition Support for Persistent Inflammation, Immunosuppression and Catabolism Syndrome

Moore FA, Phillips SM, McClain CJ, Patel JJ, Martindale RG

Review article: Nutr Clin Pract. 2017 Apr;32(1_suppl): 121S-127S

https://www.ncbi.nlm.nih.gov/pubmed/28166447

• Background

In patients with multiple organ failure (MOF), the development of persistent inflammation, immunosuppression, and catabolism syndrome (PICS) is associated with a poor outcome. Nutrition support may help to combat the effects of PICS in the ICU.

• Methods

A literature review/opinion article.

• Results

Although MOF has been recognized since the 1970s, PICS has emerged more recently as a chronic phenotype. PICS patients often suffer from nosocomial infections, sepsis, poor wound healing, and pressure ulcers, and often die an indolent death after discharge from the ICU. Experiments in murine models of sepsis and trauma have prompted the hypothesis whereby expansion of myeloid-derived suppressor cells account for the features of PICS. In this syndrome, cachexia and catabolism are driven by (and anabolism is blocked by) low-grade inflammation. Although early enteral nutrition improves infection prevention, mucosal perfusion, intestinal transit and mucosal permeability, it fails to prevent catabolism. Given the similar profiles of cachexia in cancer and in PICS, at least 1.2–2.0 g/kg/d of protein has been recommended. However, the use of arginine supplementation in sepsis is controversial because it might result in increased NO levels and thus amplification of septic shock. However, this scenario has not been proven in the clinic. A trial of parenteral nutrition with branched-chain AAs found improvements in biochemical markers but not in hard outcomes like mortality. Anabolic interventions (e.g. intensive insulin therapy, oxandrolone, propranolol, and strength training) have not been extensively studied in PICS but could easily be applied.

• Conclusion

High-protein diets supplemented with leucine (to promote anabolism) and arginine (to block the expansion myeloid-derived suppressor cells) have a theoretical basis in the management of PICS. Further research on the value of anabolic adjuncts is required.

Study Protocol

Design and implementation of Pharyngeal electrical Stimulation for early de-cannulation in TRACheotomized (PHAST-TRAC) stroke patients with neurogenic dysphagia: a prospective randomized single-blinded interventional study

Dziewas R, Mistry S, Hamdy S, Minnerup J, Van Der Tweel I, Schäbitz W, Bath PM; PHAST-TRAC Investigators

Int J Stroke. 2017 Jun;12(4):430-437

https://www.ncbi.nlm.nih.gov/pubmed/27807279s

• Background

Post-stroke dysphagia is associated with elevated mortality, morbidity, and healthcare system costs. Stroke patients weaned off mechanical ventilation often require tracheotomy to prevent aspiration. Pharyngeal electrical stimulation (PES) may enable tracheotomized stroke patients with dysphagia to regain sufficient airway control and thus to achieve decannulation (removal of the tracheotomy tube).

• Methods

A prospective international multicenter single-blind, randomized controlled trial has been designed to assess the safety and efficacy of PES in accelerating dysphagia rehabilitation and enabling decannulation of tracheotomized stroke patients. The main inclusion criteria are as follows hemorrhagic or ischemic stroke, mechanical ventilated for at least 48 h, post-stroke tracheotomy, weaning off mechanical ventilation, and ineligible for decannulation at least 10 days after the stroke event and then between 24 and 72 h after the first decannulation. The patients will be randomized into an "early" group (PES within 24 h of randomization) and a "late" group (PES 132–252 h after randomization). PES will be applied for 10 minutes a day for three consecutive days, using the Phagenyx™ system. Approximately 126 ICU patients (the 90th percentile of the calculated maximum sample size) should be included in the trial.

• Results

Given that this publication reports on the trial's design, the present section will describe the planned efficacy and safety criteria. The primary endpoint will be the proportion of stroke patients in whom decannulation is considered to be safe after PES (vs. no PES). The main secondary endpoints will be the severity of dysphagia, the decannulation rates, the decannulation rate after repeated PES in patients with persistent dysphagia after initial PES, stroke severity, the length of stay in the ICU, the occurrence of adverse events (including pneumonia), and the need for recannulation over 30 days or until discharged from hospital.

• Conclusion

This single-blind, randomized controlled trial has been designed to robustly evaluate whether PES can improve airway safety and enable earlier tracheotomy tube removal.

Study Summary

Dysphagia in Mechanically Ventilated ICU Patients (DYnAMICS): A Prospective Observational Trial

Schefold JC, Berger D, Zürcher P, Lensch M, Perren A, Jakob SM, Parviainen I, Takala J

Crit Care Med. 2017 Dec;45(12):2061-2069
https://www.ncbi.nlm.nih.gov/pubmed/29023260

• Background

invasive mechanical ventilation in critically ill patients is associated with an increased incidence of swallowing disorders, which in turn is associated with worse outcomes.

• Methods

This prospective observational trial was designed to (i) describe the incidence and time course of dysphagia in extubated adult patients hospitalized in an intensive care unit (ICU), and (ii) estimate the putative association between dysphagia and poor clinical outcomes. Primary ICU admissions were monitored for 90 days after admission or until death. Within 3 hours of extubation, dysphagia was screened for at the bedside by trained ICU nurses.

• Results

A mixed ICU population of 1304 patients (median [interquartile range (IQR)] = 66 [54–74]) was screened, and 933 primary ICU admissions were included in the analysis. The median [IQR] Acute Physiology and Chronic Health Evaluation-II score was 19 [14–24]. Ninety-six of the 933 patients had dysphagia, giving an incidence of 10.3%. Fifty-eight of these 96 patients (60.4%) remained dysphagic until discharge. Dysphagia was associated with significantly more days on a feeding tube, more days on mechanical ventilation, a longer length of stay in the ICU, a longer hospital length of stay, and a higher in-hospital mortality rate($p<0.001$ for all). The univariate hazard ratio [95% confidence interval] for 90-day mortality in dysphagic patients was 3.74 [2.01–6.95] ($p<0.001$). After adjusting for disease severity and the duration of mechanical ventilation, dysphagia was still an independent predictor of 28- and 90-day mortality. The excess 90-day mortality rate was 9.2%.

• Conclusion

Dysphagia after extubation was common in ICU patients. In the majority of sufferers, the condition was still present at hospital discharge. Dysphagia is an independent predictor of in-hospital death.

Study Summary

Real-World Effectiveness of a Medically Supervised Weight Management Program in a Large Integrated Health Care Delivery System: Five-Year Outcomes

Krishnaswami A, Ashok R, Sidney S, Okimura M, Kramer B, Hogan L, Sorel M, Pruitt S, Smith W

Perm J. 2018;22:17-082

https://www.ncbi.nlm.nih.gov/pubmed/29401050

• Background

Data on the long-term efficacy of behavior-based treatment of obesity are scarce.

• Methods

This was a US, retrospective, observational, five-year study of adult participants (aged 18 and over, body mass index either ≥ 30 with no comorbid conditions or ≥ 28 with two comorbid conditions) in an 82-week, behaviorally-based, medically supervised weight management program (enrolled in a large integrated healthcare delivery system weight management program). The program consisted of a complete meal replacement (Optifast®) phase (for ≤16 weeks), a transition phase (from 17 to 29 weeks), and a life-style maintenance phase (from 30 to 82 weeks). Pharmacologic and surgical treatment, and psychiatric disease were exclusion criteria of the program.

• Results

A total of 10,693 participants were enrolled in the study, and five-year data were available for 2,777 of these (women: 72.8%; mean (standard deviation) age: 51.1 (12.4); mean (standard error) weight at baseline: 112.8 kg (0.23)). Bodyweight fell significantly after initiation of the program, with a mean (standard error) change from baseline of -17.3 kg (0.12) after 4 months, -14.2 kg (0.12) after 1 year, -8.6 kg (0.14) after 2 years, -6.9 kg (0.17) after 3 years, -6.5 kg (0.16) after 4 years, and -6.4 kg (0.29) after 5 years.

• Conclusion

An 82-week medically supervised weight management program utilizing initial 4 months of total meal replacements and weekly group behavior changes sessions resulted in significant early and long-term weight loss. Average percentage weight loss after 4 months was 15.3% and average weight loss at 5 years remained both clinically and statistically significant (-5.8%; $p<0.05$). At 5 years, approximately 50% of the participants achieved -5% weight loss from baseline or more, which is a clinically significant weight loss. Results from the study reinforce the strength of a standardized long-term behavior change intervention plus a meal replacement program in subjects with obesity and overweight.

Study Summary

Effects of 3-Week Total Meal Replacement vs.Typical Food-based Diet on Human Brain Functional Magnetic Resonance Imaging Food-cue Reactivity in Subjects with Obesity: A Randomized Controlled Trial

Kahathuduwa CN, Davis T, O'Boyle M, Boyd LA, Chin SH, Paniukov D, Binks M

Appetite. 2018 Jan 1;120:431-441

https://www.ncbi.nlm.nih.gov/pubmed/28958900

• Background

There are few data on human brain fMRI food-cue reactivity (fMRI-FCR) and functional connectivity data in a context of food craving. These parameters were examined and compared in a trial of a total meal replacement (TMR, Optifast®) program vs. a typical reduced-calorie diet (TD).

• Methods

fMRI-FCR, functional connectivity, food cravings (in the Food Craving Inventory) and weight were assessed before and after the interventional period in a randomized repeated measures study with an interventional group (a 3-week TMR program with shakes) and a control group with portion control (TD). The calorie supply was 1120 kcal/day.

• Results

32 participants (age range 19-60; BMI: 30-39.9 kg/m2) were randomized. After the intervention, the participants in the TD group displayed (i) increased FCR (relative to the TD group and the FCR before the intervention) in the bilateral dorsolateral prefrontal cortices (dlPFC), orbitofrontal, anterior cingulate, primary motor and left insular cortices, and bilateral nucleus accumbens, and (ii) negative modulation of FCR of the nucleus accumbens, orbitofrontal cortex and amygdala by the dorsolateral prefrontal cortices. Body weight loss and body fat in the TMR group (4.87 kg and 2.19 kg, respectively) were significantly greater than in the TD group (2.37 kg and 1.64 kg, respectively). A marked reduction in overall food cravings was observed in the TMR group (0.41, p=0.047).

• Conclusion

A TMR may be associated with greater executive control than a TD, as evidenced by reduced food cravings, greater weight loss, increase food-cue reactivity and greater down-modulation of food-reward-sensitive regions by the dorsolateral prefrontal cortex.

Study Summary

Medical Weight Management Program Is Associated with Reduced Healthcare Insurance Claims Cost

Ard JD, Pajewski NM, Hale E, Frain A, Miret M

Congress Abstract - Obesity Week 2017, Washington DC

https://obesityweek.com/abstract/medical-weight-management-program-is-associated-with-reduced-healthcare-insurance-claims-cost/

• Background

Multidisciplinary weight management programs (WMPs) may constitute a means of lowering the significant healthcare costs associated with obesity.

• Methods

In a study performed in the USA, a dataset of health insurance claims from 2013-2015 were analyzed in an interventional group (n=306) and a control group (n=927) of healthcare organization employees and their dependents. The intervention consisted of a 52-week individual- and group-based WMP with meal replacements (Optifast®) and multidisciplinary care, implemented during the period 2010-2012. The participants in the control group did not participate in the WMP.

• Results

The mean baseline characteristics of the interventional group were as follows: age: 46.3±10.3; BMI: 39.8±7.2 kg/m^2; women: 84%; African-American ethnicity: 18%). The WMP resulted in the loss of 14.5±8.5% of baseline bodyweight after 52 weeks. In the two years after implementation of the WMP (2013-2015), the mean [95% confidence interval] pooled medical and pharmacy costs were significantly lower in the interventional group than in the control group (with a difference of 22,348 [17,094–27,546] USD. However, these costs were also lower in the interventional group before the WMP, with a difference of 7,483 [4,423–10,527] USD). Nevertheless, the mean [95%CI] costs after adjustment were still lower in the interventional group (difference: 3,509 [879–6,068] USD).

• Conclusion

On the basis of health insurance claims, significant medical and pharmacy cost savings were observed in a 52-week multidisciplinary WMP that included meal replacements.

Study Summary

Long-Term Benefits Aside from Weight Loss in a Behavior Based Medically Supervised Weight Management Program: Insights from the TRANSFORM Study

Smith W, Ashoki R, Krishnaswami A, Pruitt SD, Okimura M, Hogan L, Kramer B, Sidney S, Sorel M

Congress Poster - Obesity Week 2016, New Orleans

http://www.obesity.org/obesity/meetings/obesity-week/archive/obesityweek-2016-abstracts Wednesday Nov 2

• Background

Data on the long-term efficacy of behavior-based treatment of obesity are scarce.

• Methods

This was a retrospective, observational, five-year study of adult participants (aged 18 and over, body mass index either ≥ 30 with no comorbid conditions or ≥ 28 with two comorbid conditions) in an 82-week, behaviorally-based, medically supervised weight management program in the San Francisco Bay area between January 2007 and December 2014. The program consisted of a complete meal replacement phase (for ≤16 weeks; mainly OPTIFAST®), a transition phase (from 17 to 29 weeks), and a life-style maintenance phase (from 30 to 82 weeks).

• Results

A total of 10,693 participants were enrolled in the study, and five-year data were available for 2,777 of these (women: 72.8%; mean (standard deviation) age: 51.1 (12.4); mean (SD) BMI at baseline: 39.7 (7.2) kg/m2; mean (standard error) weight at baseline: 112.8 kg (0.23)). The program was associated with clinically significant weight loss, with a mean (standard error) change from baseline of -6.4 kg (0.29) at 5 years; 46% of subjects lost more than 5% of their initial body weight (i.e. a medically significant weight loss). Mean total cholesterol levels, LDL-cholesterol levels, the TG/HDL-cholesterol ratio, the frequency of primary care and ambulatory visits, and medication use were all significantly lower ($p<0.001$) than the mean baseline values at 5 years. Systolic blood pressure had changed significantly ($p<0.001$) at 4 months, 1 years, 2 years, 3 years and 4 years but not at 5 years. Healthcare utilization "touches" were also significantly lower than baseline at all time points.

• Conclusion

In a medically supervised weight management program, clinically significant weight loss in almost half of the participants was associated with sustained blood lipid improvement, reduced medication usage, and fewer primary care and ambulatory visits.

Study Summary

Effects on Diabetes Medications, Weight and Glycated Hemoglobin Among Adult Patients With Obesity and Type 2 Diabetes: 6-Month Observations From a Full Meal Replacement, Low-Calorie Diet Weight Management Program

Shiau JY, So DYF, Dent RR

Can J Diabetes. 2018 Feb;42(1):56-60

https://www.ncbi.nlm.nih.gov/pubmed/28600119

• Background

Obesity and diabetes are strongly related; 80-90% of people with type 2 diabetes are overweight or obese. In patients with type 2 diabetes, meal replacements have been shown to produce greater weight losses than individualized diet plans.

• Methods

In a Canadian retrospective cohort study (1992-2009) of patients with obesity and type 2 diabetes, weight loss, hypoglycemic medication use and glycemic control were studied in a full meal replacement (MR) program (900 kcal and 90g protein/day for 6-12 weeks, followed by a transition to regular food. Patients were encouraged to decrease or discontinue weight-gaining (WG) diabetic medications first and then weight neutral (WN) medications.

• Results

At 6 months, both groups lost 16% weightand decrease or discontinuation of medications were: 92.1% sulfonureas, 86.5% insulin, 78.8% thiazolidinediones, 77.8% alpha-glucosidase inhibitor, 50% meglitinides, 33.3% DPP4 inhibitors, and 32.8% metformin.

- At 6 months compared with baseline, A1C improved in Group WG and Group WN (A1C 6.7% and 5.8% respectively, $p<0.0001$) with Group WN having significantly better A1C than Group WG.
- At 6 months, 30% of patients were no longer on diabetes medications and had significantly better % weight loss compared with those on medications (18.6% vs 16%, $p=0.002$); both groups had improved glycemic control at 6 months (A1C 6.0% vs A1C 6.6%, NS).

• Conclusion

In patients with obesity and type 2 diabetes on medications, a full MR program appears safe with A1C improvement. At 6 months, % weight loss can be significantly better in patients who no longer require diabetes medications and A1C is best controlled in patients who are on WN medications.

Study Summary

Consumption of High Protein Meal Replacements Improves Glycemic Response in Type 2 Diabetic Adults

Periman SA, Neutel J, Cohen SS, Ochoa Gautier JB

Congress Poster - Obesity Week 2017, Washington DC

https://obesityweek.com/abstract/consumption-of-high-protein-meal-replacements-improves-glycemic-response-in-type-2-diabetic-adults/

• Background

Overweight/obesity is associated with type 2 diabetes mellitus (T2DM). Meal replacements are often included in medically supervised weight management programs that include people with T2DM.

• Methods

The objective of this controlled, randomized clinical trial with a cross-over design in adults with controlled T2DM was to determine whether or not four different types of high-protein (40%) meal replacement products (OPTIFAST®) can improve postprandial blood glucose, relative to two isocaloric control products. Each participant consumed a meal following an overnight fast on six different days. There was a one-week interval between each experiments. Blood glucose and insulin levels were measured at 0, 10, 20, 30, 60, 90, 120, 150, 180, 210, and 240 minutes post-meal, and the respective areas under the curve (AUC) and peak concentrations (Cmax) were calculated. Antidiabetic medications were prohibited during the test period.

• Results

Thirteen adults (9 women, 4 men; age: 61.0 ± 8.3; BMI: 32.3 ± 5.7 kg/m^2) performed the study. The AUC and Cmax for glucose (but not for insulin) were significantly lower (relative to the controls; $p<0.05$)) for the four investigated meal replacements. Tolerability was good.

• Conclusion

The glycemic response in adults with controlled T2DM was improved after the consumption of nutritionally complete meal replacements, as compared with two isocaloric control products.

Study Summary

Plasma glucose and insulin response in two oral nutrition supplements in adults with type 2 diabetes mellitus

Huhmann MB, Smith KN, Schwarz SL, Haller SK, Irvin S, Cohen SS

BMJ Open Diabetes Research and Care. 2016;4:e000240

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5013356/

• Background

In type 2 diabetes, oral nutritional supplements may improve glucose stabilization and management.

• Methods

A randomized, cross-over trial compared two oral nutritional supplements in terms of glucose and insulin levels after consumption of the beverage. Patients with type 2 diabetes consumed isocaloric amounts of the standard oral nutritional supplement and (one week apart) a diabetes-specific formula. Glucose and insulin levels were measured just before consumption and then at several time points in the 4 hours after consumption.

• Results

Twelve patients (M/F: 7/5) participated in the study. The mean glucose area under the curve (AUC) was lower in the diabetes-specific supplement group than in the standard group ($p<0.0001$). There was no significant intergroup difference for the insulin AUC ($p=0.068$) initially, although the removal of a potential outlier led to a significant intergroup difference ($p=0.012$). There were no significant intergroup differences in the insulinogenic index or the first-phase insulin measurements.

• Conclusion

In people with type 2 diabetes, a diabetes-specific oral nutritional supplement appears to provide better glucose maintenance than a standard supplement did.

Article Summary

Evidence-based recommendations and expert consensus on enteral nutrition in the adult patient with diabetes mellitus or hyperglycemia

Sanz A, Alvarez J, Ballesteros MD, Botella F, Leon M, Martın A, Martınez MA, Olveira G

Recommendations: Nutrition. 2017 Sep;41:58-67

https://www.ncbi.nlm.nih.gov/pubmed/28760429

• Background

Hyperglycemia due to stress or diabetes mellitus is a problem in (often critically ill) patients receiving enteral nutrition.

• Methods

In a Delphi survey with the GRADE criteria, Spanish experts evaluated studies and developed evidence-based recommendations for glycemic control in patients receiving EN.

• Results

The experts made the following evidence-based recommendations on EN and glycemic control: (i) apply the same metabolic control targets as in all patients with diabetes; (ii) apply the same caloric targets as in patients without diabetes but with the same clinical condition; (iii) determinations of macronutrient content should be based on an individualized assessment taking account of clinical status; (iv) diabetes-specific EN formulas should contain low-glycemic-index carbohydrates and a moderate or high percentage of monounsaturated fatty acids; (v) specific EN formulas for diabetes should contain fiber, although the latter does not necessarily reduce postprandial glycemia; (vi) diabetes-specific high-protein formulas should be used in mechanically ventilated patients with a view to both improved metabolic control and a reduced incidence of respiratory infections; (vii) diabetes-specific EN formulas should be used in homecare; (viii) in hospitals, insulin therapy with basal-bolus regimens should be used for hyperglycemia patients, (ix) the postpyloric administration route is strongly recommended in patients with diabetic gastroparesis, and it is not clear whether extra supplementation with vitamins and/or minerals is of value.

• Conclusion

Evidence-based recommendations on EN in patients with diabetes and hyperglycemia are available, Characteristics of diabetes-specific formulas are described in this review.

Study Summary

Consumption of high protein meal replacements improves glycemic response in type 2 diabetic adult patients

Periman S, Neutel J, Cohen SS, Ochoa Gautier JB

Congress Abstract - Obesity Week 2017, Washington DC

https://obesityweek.com/abstract/consumption-of-high-protein-meal-replacements-improves-glycemic-response-in-type-2-diabetic-adults/

• Background

Type 2 diabetes mellitus is associated with weight gain. Meal replacements constitute one component of a medically managed weight loss program to counter weight gain. It is possible that meal replacement products designed to improve glycemia control may be associated with better heath outcomes than those not designed in this respect.

• Methods

The objective of this randomized, crossover trial in adults with controlled type 2 diabetes was to assess glycemia control and insulin responses following the ingestion (after an overnight fast) of six complete meal replacements on six separate days a week apart. The six complete meal replacements comprised four OPTIFAST® complete (high-protein) meal replacements and two other meal replacement products (controls). Blood glucose and insulin levels were assayed at 11 time points after ingestion: 0, 10, 20, 30, 60, 90, 120, 150, 180, 210 and 240 minutes. For both blood glucose and blood insulin, the peak concentration (Cmax) and the area under the curve (AUC) were calculated.

• Results

Thirteen individuals (9 females, 4 males) participated in the trial. The mean age was 61 and the mean body mass index was 32.3 kg/m^2. For glucose, the AUC and Cmax were significantly lower ($p<0.0001$) for the four OPTIFAST® complete meal replacements than for the control products. For insulin, there were no differences between the products in terms of the AUC and Cmax.

• Conclusion

In a randomized, crossover trial, individuals with type 2 diabetes displayed a better glycemic response after consuming four OPTIFAST® high-protein complete meal replacements than after consuming two control meal replacement products.

Study Summary

Cost effectiveness of Optifast® LCD as compared with Liraglutide 3 mg and "no intervention" in Switzerland

Nuijten M, Marczewska AM, Araujo Torres K, Morton M, Perugini M

Congress Abstract - ISPOR 2017 20th Annual Congress - Glasgow

http://www.valueinhealthjournal.com/article/S1098-3015(17)31219-6/fulltext

• Background

Obesity is associated with high direct and indirect costs related to increased healthcare utilization and productivity loss. Optifast® total meal replacement Low Calorie Diet is an effective weight management program for people with obesity (BMI>30 kg/m^2) that results a significant weight loss at a rate of ≈ 1 kg per week. This health economic model aims to demonstrate potential cost savings achieved with Optifast® program in Switzerland, as compared to the absence of intervention and pharmacotherapy with liraglutide 3 mg in people with obesity from payers' and employers' perspectives.

• Methods

An event-driven decision model to estimate the cost-effectiveness of one-year Optifast® program over a 10-year period, as compared to (i) the absence of intervention and (ii) pharmacologic treatment with liraglutide 3 mg in obese subjects. Data were sourced from the scientific literature, clinical trials, price/tariff lists and population statistics.

• Results

Optifast® one-year program reduces the cost of obesity complications, leading to cost savings for payers (CHF 5,623) and employers (CHF 30,307) in Switzerland over 10 years versus the absence of intervention. Compared to liraglutide 3 mg, Optifast® leads to additional cost savings for payers (CHF 9,732) and employers (CHF 14,187) over the same time period. Scenario analyses show additional cost savings in patients with severe obesity (BMI>40 kg/m^2), and with T2 diabetes mellitus.

• Conclusion

Reimbursing Optifast® leads to meaningful costs savings for payers and employers in Switzerland, as compared to liraglutide 3 mg and with the absence of intervention in subjects with obesity. Similar results could be expected in countries with matching healthcare settings.

Study Summary

Immunonutrition and pre surgical wellness, critical elements in the pathway improved outcomes, reduced surgical site infection, length of stay, and readmission independents of enhanced recovery enhancing a proactive culture of safety

Tran B, Gupta V, Strange N, Wooden W

Congress Abstract - ASER 2017 - Washington

http://aserhq.org/wp-content/uploads/2017/07/19_ASER_Tran.pdf

• Background

A high proportion of surgical patients have risk factors for complications. In 2011 to 2015, the Indiana University Health Adult Academic Health Center progressively initiated the POWERR pre-surgical program for enhanced recovery after surgery. It comprised immunonutrition (IMPACT® AR for the five days before surgery), general nutrition, carbohydrate loading, physical activity, smoking cessation, chlorohexidine soap bathing, mupirocin treatment and other procedures.

• Methods

The investigators retrospectively reviewed charts of surgical patients. The length of stay (in the ICU and in hospital), mortality, and surgical site infections were assessed for each year as the program was progressively reinforced.

• Results

The length of stay index fell from 1.142 in 2013 to 1.32 in 2014, 1.064 in 2015, and 1.063 in 2016. The mean length of stay in the ICU fell from 6.22 days in 2012 to 5.99 in 2015. The mortality index fell from 1.33 in 2012 to 1.11 in 2013 and 2014, and 0.97 in 2015. The superficial surgical site infection rate fell from 7.89% in 2010 to 1.72% in 2016 for colectomy, from 6.25% to 0% for enterectomy, from 17.14 to 7.14% for gastrectomy, from 6.74% to 2.33% for hepatectomy, from 5.15% to 1.75% for pancreatectomy, and from 11.11% to 0% for proctectomy. The deep surgical site infection rate fell from 1.12% in 2010 to 0% in 2016 for hepatectomy and from 1.03% to 0.58% in those years for pancreatectomy.

• Conclusion

An immunonutrition- and wellness-based program for enhanced recovery after surgery markedly improved outcomes in a US academic health center.

Study Summary

Advancing surgical outcomes by providing patients with core elements and standardized preoperative wellness education

Tran B, Gupta V, Strange N, Wooden W

Congress Abstract - ASER 2017 - Washington

http://aserhq.org/wp-content/uploads/2017/07/18_ASER_Tran.pdf

• Background

A high proportion of surgical patients have risk factors for complications (primarily infections), which are associated with a longer length of stay, increased morbidity and mortality, and worse quality of life. In 2011 to 2015, the Indiana University Health Adult Academic Health Center progressively initiated the POWERR pre-surgical program for enhanced recovery after surgery. It comprised immunonutrition (based on arginine, omega-3 fatty acids, and nucleotides for the five days before surgery IMPACT® AR), general nutrition, carbohydrate loading, physical activity, smoking cessation, chlorohexidine soap bathing, mupirocin treatment and other procedures.

• Methods

This was a retrospective chart review of surgical patients having attended a pre-admission testing clinic at academic health centers in late 2015 or in 2016. During the subsequent admission assessment, patients were queried about compliance with the POWERR program.

• Results

A total of 6834 adults undergoing elective surgery were included in the study. 91.1% of the patients had received at least 1 component of the POWERR program. The overall compliance rate was 57%. The compliance rates for program components were 47.1% for immunonutrition, 49.5% for an incentive spirometer, 52.8% for chlorhexidine bathing, and 68% for mupirocin use. Overall, compliance with the POWERR components was associated with a significant decrease in the post-surgical complication rate. The global harm event rate was 39% lower in POWERR-compliant patients.

• Conclusion

Compliance with the POWERR immunonutrition and pre-surgical patient education program was associated with better outcomes and a significantly lower incidence of post-operative complications.

Study Summary

Cost consequence analysis of immune-enhancing nutritional formula in patients with digestive cancer surgery

Danel A, Viana SD, Dias A, Lopez SN, Tauil DA, Meale MM

Congress Poster (PCN29) - ISPOR LATAM 2017 - Sao Paulo

http://www.valueinhealthjournal.com/article/S1098-3015(17)32915-7/abstract

• Background

Postsurgical infectious complications can increase the use of healthcare resources. Immune-enhancing nutritional formulas may decrease infectious complications and the hospital length of stay.

• Methods

The objective of this health economic study in Brazil was to determine the impact of the use of an immune-system enhancing nutritional formula (IMPACT®) on hospital costs, relative to the standard of care. The study population comprised cancer patients undergoing elective gastrointestinal surgeries. The nutritional intervention was administered three times a day for the 5 days immediately before surgery.

• Results

Infectious complications increased the cost of a hospital stay by 50% (to a total of 10,007 Brazilian reals (BRL). The administration of an immune-enhancing nutritional formula resulted in per patient savings of BRL 272 (when considering costs related to infectious complications) and BRL 1223 (when considering costs related to the length of stay).

• Conclusion

The presurgical administration of an immune-system-enhancing nutritional formula IMPACT® to cancer patients undergoing elective gastrointestinal surgery was associated with overall cost savings, due to fewer infectious complications and a shorter length of stay.

Study Summary

Impact of arginine-based immunonutrition on inpatient total costs and hospitalization outcomes for patients undergoing colorectal surgery

Banerjee S, Garrison LP, Danel A, Ochoa Gautier JB, Flum DR

Congress Poster (PHP89) - ISPOR US 2017 - Boston

https://www.ispor.org/ScientificPresentationsDatabase/Presentation/72710

• Background

Immune-system-enhancing nutritional intervention prior to surgery may modify healthcare resource use and costs.

• Methods

This was a health economics study (database analysis) of adult patients having undergone elective colorectal surgery involving anastomosis in hospitals in Washington State (USA). The objective was to assess the impact of arginine-based nutritional intervention (IMPACT Advanced Recovery® Immunonutrition Drink three times a day for the five days immediately before surgery) on post-operative resource use and outcomes. The immunonutrition group was compared with a standard-diet control group (n=565). The data were adjusted for the patients' demographic and clinical characteristics, using a multivariate regression model.

• Results

A total of 722 adults were included (n=151 in the immunonutrition group and n=565 in the control group). The surgical site infection rate was zero in the immunonutrition group and 2.65% in the control group (p=0.04). The venous thromboembolism rate was also significantly lower in the immunonutrition group (1.32%) than in the control group (4.96%; p=0.05) The postsurgery readmission rates were 50-58% lower in the immunonutrition than in the control group. After adjusting for demographic and clinical factors, the readmission rates were still lower at 30 ($p<0.05$), 90 and 180 days (both $p<0.01$) post-discharge. The mean cost of care up to 180 days post-discharge was 5300 USD lower in the immunonutrition group than in the control group.

• Conclusion

The use of IMPACT Advanced Recovery® Drink as a nutritional intervention was associated with cost savings and clinical benefit in adult patients having undergone colorectal surgery.

Study Summary

Effects of arginine-based immunonutrition on inpatient total costs and hospitalization outcomes for patients undergoing colorectal surgery

Banerjee S, Garrison LP, Danel A, Ochoa Gautier JB, Flum DR

Nutrition. 2017 Oct;42:106-113

https://www.ncbi.nlm.nih.gov/pubmed/28734748

• Background

Arginine-based immunonutrition intervention may influence post-surgical and cost outcomes for patients undergoing elective colorectal surgery.

• Methods

This was an analysis of two databases generated in Washington State (USA): the Surgical Care and Outcomes Assessment Program and the linked Comprehensive Hospital Abstract Reporting System. The study population comprised adult patients having undergone elective colorectal surgery with anastomosis in a participating hospital in Washington State in 2012 or 2013, divided into an intervention group (arginine-based immunonutrition) and a control group. Outcomes were studied in a generalized linear model after adjustment for health conditions and demographic characteristics.

• Results

In the 180 days after the index hospitalization, the number of re-admissions and days in hospital and the incidence of infections and venous thromboembolic events were significantly lower in the intervention group. Although the intervention vs. control differences in mean total costs per patient were substantial (savings of around $2,500 at index hospitalization, $3,500 after 30 days, and $5,300 after 180 days), they were not statistically significant.

• Conclusion

Arginine-based immunonutrition after elective colorectal surgery was associated with substantial costs savings (albeit not statistically significant in this study) and should be evaluated further.

Study Summary

Adherence and tolerance as key in brake on weight loss in cancer patients with nutritional risk after intervention with a high calorie nutritional and specific hyperproteic supplement

García JM, Lupiáñez Y, Blanco M, Ruiz J, Medina JA, Cornejo I, Gómez A, Molina M, López JA, Tinahones F

Nutr Hosp. 2017 Jun 5;34(3):524-531

https://www.ncbi.nlm.nih.gov/pubmed/28627185

• Background

Weight loss is a major problem during cancer treatment. Nutritional supplements may help to counter weight loss in this setting.

• Methods

The investigators performed a prospective, observational, single-center study of a six-day course of low-volume nutritional supplementation in patients being treated for lung, ENT and breast cancers and presenting with malnutrition or a risk of malnutrition. The nutritional supplement was rich in protein, calories and omega-3 fatty acids. The study endpoints were treatment compliance (packaging survey), acceptability, anthropometric variables and the occurrence of gastrointestinal tract adverse events.

• Results

A total of 30 patients (21 men, 9 women; mean (range) age: 60 (32-79)) were included. The cancers mainly concerned the lung (43.3%), the ENT region (26.7%), and the breast (13.3%). The cancers were staged at III-IV in 56.7% of cases. The treatments included radiotherapy (in 93.3% of patients), chemotherapy (in 60%) and surgical resection (in 16.7%). Treatment compliance was 100%. Two patients (6.7%) experienced a gastrointestinal tract adverse event but both had a preexisting gastrointestinal condition. The median weight, body mass index and protein intake increased during the nutritional supplementation (by 0.2 kg, 0.1 kg/m^2 and 6.2 g, respectively) but the calorie, fat and carbohydrate intakes did not change markedly.

• Conclusion

A specific nutritional supplement for cancer patients was well accepted and led to weight gain. Gastrointestinal adverse events were rare and only affected patients with a preexisting gastrointestinal condition.

Study Summary

Nutritional counseling with or without systematic use of oral nutritional supplements in head and neck cancer patients undergoing radiotherapy

Cereda E, Cappello S, Colombo S, Klersy C, Imarisio I, Turri A, Caraccia M, Borioli V, Monaco T, Benazzo M, Pedrazzoli P, Corbella F, Caccialanza R

Radiother Oncol. 2018 Jan;126(1):81-88

https://www.ncbi.nlm.nih.gov/pubmed/29111172

• Background

In head and neck cancer (HNC) patients, weight loss, low body mass index and reduced protein-calorie intake before and/or during radiotherapy (RT) have been associated with worse survival, locoregional treatment failure, impaired quality of life (QoL), greater toxicity and severe mucositis. Early intervention with energy-dense, high-protein oral nutritional supplements (ONSs) may counter (in part) these negative effects.

• Methods

This single-center, parallel-group, randomized controlled trial in adult patients with newly diagnosed HNC sought to evaluate the benefit of personalized dietary prescription plus administration of an ONS (2 bottles per day of Resource® Support Plus; 500 kcal, 23 g of protein and 1.9 g of omega-3 fatty acids, in the intervention group) or personalized dietary prescription alone (the control group). Body weight, QoL, functional status and treatment tolerance were evaluated during RT and in the 3 months thereafter.

• Results

159 patients were randomized to nutritional counseling + ONS (n=78) or nutritional counseling alone (n=81). In the ONS arm, compliance was fair (mean (SD) of 1.2 (0.6) bottles per day, rather than 2). Safety was good, and no hospitalizations were related to the nutritional intervention. The mean [95%CI] change in body weight at the end of RT was smaller in the ONS group (1.9 kg [2.7 to 1.1]) than in the control group (3.5 kg [4.2 to 2.7]; p=0.006). Patients receiving the ONS were less likely to require RT dose reduction or cessation (9.0%, vs. 22.0% of the controls; p=0.029).

• Conclusion

The use of ONSs in addition to nutritional counseling reduced body weight loss in HNC patients and improved QoL and RT tolerance.

Study Summary

Serum 7C4 levels decrease after low FODMAP diet in IBS patients: a potential mechanism for benefit

Eswaran SL, Selvaraj FM, Princen F, Tooker P, Harvie G, Chey WD

Congress Abstract - Digestive Disease Week 2017 - Chicago

http://www.gastrojournal.org/article/S0016-5085(17)30857-0/fulltext

• Background

Patients suffering from irritable bowel syndrome may benefit from a diet low in fermentable, oligo-, di-, mono-saccharides and polyols (FODMAPs). Although the underlying mechanism has not been characterized, bile acid metabolism may be involved. 7-α-hydroxy-4-cholesten-3-one (7C4) may be a serum marker for bile acid malabsorption.

• Methods

In a prospective, single-blind, randomized controlled trial, adults with irritable bowel syndrome and diarrhea were randomized to four weeks on a low FODMAP diet or a diet based upon the modified NICE (mNICE) guidelines. In a post-hoc analysis, intergroup differences from baseline in serum 7C4 levels before and after the dietary intervention were assessed.

• Results

A total of 92 patients were randomized (females: 71%; median (range) age: 42.6 (19-75); Caucasians: 74%), and 83 completed the study period (45 in the low FODMAP group and 38 in the mNICE group). Baseline serum 7C4 levels were similar in the two groups. After the intervention, 7C4 levels had fallen significantly in the low FODMAP group (-1.257 ng/ml from baseline; $p<0.0001$) and had risen non-significantly in the mNICE group (+1.222 ng/ml from baseline; $p=0.4519$). In the low FODMAP group, individuals with a reduction in abdominal pain had a greater decrease in 7C4 levels (-2.112 ng/ml; $p= 0.0885$) than those without a reduction in abdominal pain (+1.193 ng/mL, $p = 0.1365$).

• Conclusion

Four weeks of a low FODMAP diet (but not an mNICE diet) led to a significant fall in serum 7C4 levels and was associated with reduced abdominal pain.

Article Summary

History of the low FODMAP diet

Gibson PR

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:5-7
https://www.ncbi.nlm.nih.gov/pubmed/28244673

• Background

the modern concept of fermentable oligosaccharides, disaccharides and monosaccharides and polyols (FODMAPs) developed historically from work on "windy" foods implicated in gastrointestinal discomfort.

• Methods

A literature review/opinion article.

• Results

In the 1960 to 1980s, it was recognized that malabsorption of various carbohydrates (lactose, fructose, sorbitol, fructo- and galacto-oligosaccharides, the polyols mannitol and xylitol, etc.) were implicated in diarrhea, pain, and bloating in healthy subjects and in symptoms of irritable bowel syndrome. Next, it became clear that all slowly absorbed or indigestible short-chain carbohydrates could result in distension of the small intestine lumen by water and/or gas production. The FODMAP acronym was adopted by a group at Monash University (Australia) in 2004, and a related FODMAP hypothesis for the pathogenesis of Crohn's disease was published in 2005. The corresponding concept of a low-FODMAP diet was spread to and by key opinion leaders in New Zealand, the UK, the USA, Denmark, Norway, Hong Kong and Switzerland, amongst others. The low-FODMAP diet prompted research into the concepts and mechanisms involved, the nutritional efficacy and safety of restricting FODMAP content, and educational methods. The low-FODMAP concept has been implemented worldwide because (i) its biological basis and dietary principles are clearly defined, and (ii) there is an extensive database on the FODMAP content of many foodstuffs.

• Conclusion

Thanks to research worldwide, the low-FODMAP diet has rapidly evolved from a set of physiological observations into an over-arching dietary concept.

Article Summary

How to institute the low-FODMAP diet

Barrett JS

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:8-10
https://www.ncbi.nlm.nih.gov/pubmed/28244669

• Background

One approach to the management of irritable bowel syndrome is a diet low in fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAPs).

• Methods

A literature review/opinion article.

• Results

Thanks to international research efforts, the creation of the FODMAP concept in 2004/2005 led to the development of the low-FODMAP diet as a treatment strategy for treating signs of irritable bowel syndrome (IBS: bloating, abdominal pain, excessive flatus, constipation, diarrhea etc.). Given that these symptoms are also present in other bowel, defecatory and cancer disorders, a positive diagnosis of IBS is a prerequisite for initiation of a low-FODMAP diet. The latter is a dietitian-directed therapy in an individual or group setting. There are various FODMAP subtypes, to which each individual will react differently. The dietitian must use his/her judgement and observations to personalize the low-FODMAP diet as required and monitor the effectiveness (via patient-rated symptom score, for example). This diet is a short-term measure; patients should be seen 4–6 weeks after the initial consultation. A lack of response to the low-FODMAP diet and to high-FODMAP challenges should trigger discontinuation. A long-term, strict low-FODMAP diet appears to have a harmful effect on the intestinal microbiome. After 4 weeks of the restrictive phase, individual tolerance should be investigated in food challenge tests.

• Conclusion

The low-FODMAP diet is an effective, management strategy for IBS. Custom modular approaches (restricting some but not all of the FODMAPs) should always be considered. A long-term, strict low-FODMAP diet is not recommended.

Article Summary

Re-challenging FODMAPs: the low FODMAP diet phase two

Tuck C, Barrett J

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:11-15

https://www.ncbi.nlm.nih.gov/pubmed/28244664

• Background

A low-FODMAP diet with strict exclusion of fermentable oligosaccharides, disaccharides, monosaccharides and polyols is usually an effective, short-term management strategy for IBS. After 4 to 6 weeks, some restrictions are lifted.

• Methods

A literature review/opinion article.

• Results

Long-term use of a low-FODMAP diet may (i) lead to harmful alterations in the colonic microbiota and (ii) be associated with a risk of nutritional inadequacy. Compliance with the diet may be worse outside the home. Fear of inadvertently consuming high FODMAP foods may impact social activities and quality of life. Rechallenge with FODMAPs is recommended in responders, and the low-FODMAP diet should be withdrawn in non-responders. Suitable rechallenge foods include honey and mango for fructose, milk for lactose, avocado and apricot for sorbitol, mushroom and cauliflower for mannitol, apple and pear for fructose + sorbitol, wholemeal bread for wheat fructan, onion/garlic for onion/garlic fructan, and lentils and chickpeas for galacto-oligosaccharides. The dietitian has a key role in helping the patient manage the rechallenge, interpret the response and build a modified FODMAP diet for long-term use. Particular problems arise in subpopulations, such as ensuring sufficient protein in the restrictive phase for vegetarians. More data are needed on doses for FODMAP reintroduction, changes over time in FODMAP tolerance, and the long-term microbiotic effects of FODMAP reintroduction.

• Conclusion

Dietitian-directed rechallenge (to correct identify dietary triggers and ensure long-term nutritional adequacy) is an essential part of the low FODMAP diet.

Article Summary

Nutritional, microbiological and psychosocial implications of the low FODMAP diet

Staudacher HM

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:16-19
https://www.ncbi.nlm.nih.gov/pubmed/28244658

• Background

A low-FODMAP diet with strict exclusion of fermentable oligosaccharides, disaccharides, monosaccharides and polyols is usually an effective, short-term management strategy for irritable bowel syndrome (IBS). However, the diet has nutritional, microbiological, and health-related consequences.

• Methods

A literature review/opinion article.

• Results

Standard clinical practice involves 4-6 weeks of a low-FODMAP diet followed by selective and/or graded FODMAP challenges, depending on individual tolerance. Four randomized clinical trials (RCTs) have investigated the effect of a short-term low-FODMAP diet on macronutrient intake. Overall, the carbohydrate intake fell (relative to controls) but total protein and fat intake did not. In terms of micronutrients, the main problem appears to be a lower calcium intake (in two RCTs). Long-term dietary intake data are now required to evaluate nutritional adequacy after FODMAP reintroduction. In terms of the microbiota, the colonic microbiota changes within days of FODMAP restriction, with a 6-fold reduction (in one study) in the relative abundance of Bifidobacteria but no significant differences in total bacteria, *Lactobacillus* or *Faecalbacterium prausnitzii* counts. Somewhat in contrast, metagenomic diversity studies have shown no change in species richness or even an increase in richness after a week or two of a low-FODMAP diet. Despite the proven health benefits of FODMAP exclusion, a low-FODMAP diet can also impact a patients' health-related quality of life due to cost concerns, the burden of implementation, and social difficulties (stress when eating out, etc.).

• Conclusion

The trial evidence so far demonstrates that the low-FODMAP diet has some short-term impacts on nutrient intake and the gastrointestinal microbiota. Long-term data are required.

Article Summary

What is gluten?

Biesiekierski JR

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1: 78-81
https://www.ncbi.nlm.nih.gov/pubmed/28244676

• Background

Gluten is a complex mixture of hundreds of related proteins, and constitutes the main storage protein (7-13% by weight) in wheat grains and other related cereal grains. In functional terms, gluten has a key role in determining the properties of dough and bread.

• Methods

A review of food science and nutrition literature.

• Results

Wheat gluten is mainly composed of gliadin and glutenin; these proteins are insoluble in water and have high levels of glutamine (38%, on average) and proline residues. The individual gluten proteins are interlinked by strong covalent and non-covalent bonds. The protein and carbohydrate composition of gluten depends on the genotype and the environmental conditions during grown. Gliadins are highly resistant to gastro-intestinal proteolysis, due to a high proline and glutamine content. Several hundred gluten peptides are predicted to be immunogenic and to trigger a T-cell-mediated immune response. Wheat grain protein also contains amylase-trypsin inhibitors and wheat germ agglutinin (an epithelium-damaging immune effector, at least *in vitro*). The daily gluten intake by a Western adult ranges from 5 to 20 g/day. Gluten-related disorders include coeliac disease, wheat allergy, and non-coeliac gluten sensitivity - although the latter entity is subject to much debate.

• Conclusion

Gluten is a complex mixture of proteins, making it hard to analyze and define. Coeliac disease and wheat allergy are proven gluten-induced disorders but the existence of non-coeliac gluten sensitivity is hotly debated.

Article Summary

Use of the low-FODMAP diet in inflammatory bowel disease

Gibson PR

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1: 40-42

https://www.ncbi.nlm.nih.gov/pubmed/28244679

• Background

A low-FODMAP diet with strict exclusion of fermentable oligosaccharides, disaccharides, monosaccharides and polyols is a short-term management strategy for irritable bowel syndrome (IBS). 30% of patients with quiescent Crohn's disease have IBS-like symptoms.

• Methods

A literature review/opinion article.

• Results

The low-FODMAP diet is receiving considerable interest from patients with inflammatory bowel diseases (IBD) who suffer from IBS-like symptoms. In an observational study based on a food frequency questionnaire, there were no significant inter-group differences in FODMAP intake between individuals with ulcerative colitis (n=64), those with Crohn's disease (n=57), and healthy controls (n=72). In another study, however, lactose malabsorption was found in over 40% of patients with Crohn's disease (n=92) or ulcerative colitis (n=56) - twice as frequently as in healthy controls (n=83) and people with functional gastrointestinal disorders (n=201). In one observational study, 88 patients with IBD followed a low-FODMAP diet for at least 6 weeks, with advice from a specialist dietitian. The severity of most symptoms and an overall symptom score fell significantly. However, a low-FODMAP diet has potential adverse effects, especially in a patient group where undernutrition is already very common before diet initiation. Furthermore, FODMAP restriction does not appear to be correlated with changes in inflammatory activity.

• Conclusion

The low-FODMAP diet can relieve IBS-like symptoms in patients with quiescent IBD, although truly high-quality evidence is lacking. A short-term, dietitian-led diet must rapidly be followed by FODMAP reintroduction in diet responders and cessation in non-responders.

Article Summary

The evidence base for efficacy of the low FODMAP diet in irritable bowel syndrome: is it ready for prime time as a first-line therapy?

Gibson PR

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:32-35
https://www.ncbi.nlm.nih.gov/pubmed/28244668

• Background

A low-FODMAP diet with strict exclusion of fermentable oligosaccharides, disaccharides, monosaccharides and polyols is usually an effective, short-term management strategy for irritable bowel syndrome (IBS).

• Methods

A literature review/opinion article.

• Results

At the time of writing, six randomized, controlled trials of the short-term efficacy and safety of the low-FODMAP diet had been performed. Three trials provided the participants with all or nearly all their food. In one of these, the participants received a control diet or a low-FODMAP diet in a random order for 21 days, washed out for at least 21 days, and then crossed over. About 70% of the patients had a reduction in symptoms during the low-FODMAP diet. Importantly, the low-FODMAP diet *per se* did not induce new symptoms. The two other studies gave partially supportive results. Three randomized controlled dietitian-led trials were also performed (mirroring real-world conditions), and compared the low-FODMAP diet with a control "healthy diet" or a probiotic diet; a response rate of around 70% was seen. Recently, a meta-analysis of six randomized controlled trials emphasized the efficacy and improved quality of life with the low-FODMAP diet. All these trials have been criticized for various reasons (small sample sizes, biased recruitment, placebos that are difficult to blind, short interventions, etc.). Observational trials have also evidenced a response rate of around 70%.

• Conclusion

The author concludes that the diet is "*ready for prime time*" but also that "*a definitive answer to whether the low FODMAP diet should be a first-line therapy for IBS cannot be given based upon hard evidence*".

Article Summary

Food regulations: low FODMAP labeling and communication goals

Méance S, Giordano J, Chuang E, Schneider H

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:62-63

https://www.ncbi.nlm.nih.gov/pubmed/28244659

• Background

A low-FODMAP diet with strict exclusion of fermentable oligosaccharides, disaccharides, monosaccharides and polyols is usually an effective, short-term management strategy for irritable bowel syndrome (IBS).

• Methods

A literature review/opinion article.

• Results

On one hand, most jurisdictions prohibit general food and food or dietary supplement products from communicating health benefits to populations with a disease or medical conditions such as IBS; that is only allowed for drugs. On the other hand, low-FODMAP products do not comply with a prime criterion for special medical purpose/medical foods – that a disease or medical condition can be managed by changing the normal diet alone. This situation could be modified through dialogue with the regulatory authorities and scientific progress in several area. Firstly, validated analyses of a food product's FODMAP content must be developed. Secondly, thresholds for qualifying a food as "low-FODMAP" must be defined. Thirdly, education for IBS sufferers and dietitians alike should be improved, notably by providing support and educational tools like smartphone applications. To promote the benefits of a low-FODMAP diet, statements like "a low-FODMAP diet helps to improve gut comfort in subjects with digestive sensitivities" should be allowed by the authorities.

• Conclusion

Although the low-FODMAP diet has gained acceptance in the patient and medical communities, a number of hurdles that limit the ability to communicate the diet's potential health benefits.

Article Summary

Coeliac disease in the 21st century: paradigm shifts in the modern age

Newnham ED

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:82-85

https://www.ncbi.nlm.nih.gov/pubmed/28244672

• Background

Until the 21st century, coeliac disease (CD) was above all observed as a profound malnutrition syndrome.

• Methods

A literature review/opinion article.

• Results

In the 21st century, CD is no longer a condition recognized solely in cases of malnutrition, malabsorption, and failure to thrive; the epidemiology has changed dramatically. Although the prescription of a gluten-free diet to a patient with malnutrition is an easy approach, there are still no double-blind, placebo controlled randomized trials of the gluten-free diet (GFD), in the management of CD. Such trials are unlikely to be organized, given the wide adoption of the GFD in CD on the basis of observational studies. However, there is a lack of consensus on the definition of "gluten-free" and the definition of a response (to the GFD or otherwise) in CD. Furthermore, an increasing proportion of patients with CD are asymptomatic - they present with few or no gastrointestinal symptoms. There is a need for validated genetic markers (e.g. HLA and non-HLA genes) and biochemical markers (such as i-FABP, antibodies against glycoprotein-2, and urinary volatile organic compounds) of treatment responses and at-risk populations. Specificity is a problem because around 50% of the population carry the CD susceptibility genotype. In a recent prospective cohort study, only 37% of newly diagnosed CD patients had achieved mucosal remission at 1 year, despite excellent dietary adherence. In general, adherence to dietary measures is non-optimal.

• Conclusion

Biochemical and genetic markers of intestinal healing will be essential for identifying severe disease courses requiring more intensive surveillance and treatment.

Article Summary

Who should deliver the low FODMAP diet and what educational methods are optimal: a review

O'Keeffe M, Lomer MC

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:23-26

https://www.ncbi.nlm.nih.gov/pubmed/28244661

• Background

A low-FODMAP diet with strict exclusion of fermentable oligosaccharides, disaccharides, monosaccharides and polyols is usually an effective, short-term management strategy for irritable bowel syndrome (IBS). However, the diet has nutritional, microbiological, and health-related consequences.

• Methods

A literature review/opinion article.

• Results

The UK National Institute for Health and Clinical Excellence has stated that dietary management should "*only be given by a healthcare professional with expertise in dietary management*". An increasing number of dietitian-led or nurse-led randomized controlled trials (RCTs) and non-RCTs (performed variously in Sweden, the UK, New Zealand, Denmark, Australia and the USA) support the use of the low-FODMAP diet in IBS. However, given that IBS now accounts for 50% of all gastroenterology diagnoses, dietetic capacity is saturated in many countries by patients requiring low-FODMAP advice. Non-dietitian-led implementation of the low FODMAP diet is not recommended by current guidelines. In response, a recent UK study compared the clinical and cost-effectiveness of a dietitian-led group pathway and conventional one-to-one dietitian-led service. On a per patient basis, group education was 50% less expensive but was just as effective clinically.

• Conclusion

Only dietitians should assess, diagnose, and initiate treatment of dietary and nutritional problems with diets such as the low-FODMAP diet but novel delivery methods (group pathways, etc.) are required to meet demand.

Article Summary

How do FODMAPs work?

Spiller R

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:36-39
https://www.ncbi.nlm.nih.gov/pubmed/28244663

• Background

A low-FODMAP diet with strict exclusion of fermentable oligosaccharides, disaccharides, monosaccharides and polyols is usually an effective, short-term management strategy for irritable bowel syndrome (IBS).

• Methods

A literature review/opinion article.

• Results

In IBS sufferers, pain tends to worsen within 90 min of eating. This increase has been ascribed to rapidly fermentable, poorly absorbed, osmotically active FODMAPs, notably including lactose in lactase-deficient subjects. The main dose-dependent) symptoms of lactose intolerance are diarrhea, abdominal cramps, flatulence, and bloating. Although FODMAPs have indirect effects through beliefs that via the brain on gut motility, the main direct causes are (i) fluid-induced distension of the small bowel, and (ii) gaseous distension of the colon due to the fermentation of unabsorbed carbohydrate. T2-weighted imaging MRI can be used to monitor the volume and diameter of the small bowel and the colon. In a recent study of the ingestion of 350 mL liquid containing 17.5 g of mannitol or 17.5 g of glucose, the researchers evidenced a rapid, 400 mL increase in small bowel volume after 1 hour with mannitol but an increase of only 60 ml with glucose. Volume changes are similar in IBS patients and healthy controls, and so the increase in pain symptoms in IBS was ascribed to visceral hypersensitivity.

• Conclusion

The recent application of MRI confirm that fructose (but not glucose) stimulates small bowel water secretion and that fructans cause bloating in the colon.

Article Summary

FODMAPs: food composition, defining cutoff values and international application

Varney J, Barrett J, Scarlata K, Catsos P, Gibson PR, Muir JG

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:53-61

https://www.ncbi.nlm.nih.gov/pubmed/28244665

• Background

A low-FODMAP diet with strict exclusion of fermentable oligosaccharides, disaccharides, monosaccharides and polyols is usually an effective, short-term management strategy for irritable bowel syndrome (IBS).

• Methods

A literature review/opinion article.

• Results

Over the last ten years, researchers worldwide (but primarily at Monash University in Australia) have used ultra-high-performance liquid chromatography to quantify the FODMAP content (in grams per serving) of hundreds of foods. This has also enabled the establishment of a threshold for each FODMAP, i.e. the level above which digestive tract symptoms are experienced. Food processing techniques and local sourcing factors influence FODMAP levels. The Monash group's values are <0.30 for oligosaccharides in core grain products, legumes, nuts, and seeds, <0.20 for oligosaccharides in vegetables, fruits, and all other products, <0.20 for sorbitol or mannitol, <0.40 for total polyols (sorbitol + mannitol), <0.15 for excess fructose (fructose minus glucose), <0.40 when excess fructose is the only FODMAP present (in fresh fruit and vegetables), and <1.00 for lactose. These analyses also show that many gluten-rich foods are also high in FODMAPs (mostly fructans), and conversely that most gluten-free grains are low in FODMAPs. Hence, the benefits of a gluten-free diet may have been (wrongly) attributed to the removal of gluten rather than to the removal of FODMAPs take. For example, wholegrain wheat bread has a high fructan content (>1.4 g per serving).

• Conclusion

Food FODMAP content can be accurately determined, and the corresponding dietary cutoffs have been tested in research studies.

Article Summary

Prebiotic inulin-type fructans and galacto-oligosaccharides: definition, specificity, function, and application in gastrointestinal disorders

Wilson B, Whelan K

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:64-68
https://www.ncbi.nlm.nih.gov/pubmed/28244671

• Background

A low-FODMAP diet with strict exclusion of fermentable oligosaccharides, disaccharides, monosaccharides and polyols is usually an effective, short-term management strategy for irritable bowel syndrome (IBS).

• Methods

A literature review/opinion article.

• Results

Most prebiotics are dietary inulin-type fructans or galacto-oligosaccharides (polymers of galactose with a terminal glucose monomer). All these compounds (i) cannot be digested by endogenous human gut enzymes, and (ii) are selectively fermented by specific gut microbiota - the increase in which confers health benefits on the host. Researchers have started to investigate the genomic determinants of prebiotic fermentation, mostly in the *Bacteroides*. For example, *Bacteroides thetaiotaomicron* has 88 polysaccharide utilization loci genes, which are controlled by 33 genes encoding hybrid two-component signaling sensors. Beta galacto-oligosaccharides specifically increase the growth rate of *Bifidobacterium* spp. In healthy subjects (and probably in IBS sufferers), inulin-type fructans ultimately having immunomodulatory properties by raising fecal levels of IgA, stimulating IL-10 and IFN-γ release by Peyer's patch cells and increasing the activity of immune cells in the spleen. *Bifidobacterium* spp. levels are already abnormally lower in IBS. However, prebiotics are FODMAPs; hence, a low-FODMAP diet in IBS restricts the intake of prebiotics, which may have negative health effects.

• Conclusion

The restriction of naturally occurring dietary prebiotics reduces some functional gut symptoms (fluid and gas bloating) in IBS but also specifically reduces *Bifidobacterium* levels, which may indirectly accentuate pain and inflammation.

Article Summary

Gluten-induced cognitive impairment ("brain fog") in coeliac disease

Yelland GW

Review article: J Gastroenterol Hepatol. 2017 Mar;32 Suppl 1:90-93

https://www.ncbi.nlm.nih.gov/pubmed/28244662

• Background

Coeliac disease (CD) is a chronic, inflammatory, autoimmune disease in which gluten ingestion has been causally linked to small bowel damage. A gluten-free diet (GFD) is often prescribed to patients with CD.

• Methods

A literature review/opinion article.

• Results

Coeliac disease has a number of known, defined neurological complications, such as gluten-related cerebellar atrophy, peripheral neuropathy, and even dementia in 2% to 10% of the CD population. However, it has been postulated that silent neurological damage (minor cognitive impairment or "brain fog") affects patients with CD. In one study based on the Subtle Cognitive Impairment Test (measuring the speed and effectiveness of cognitive processing), the cognitive performance of 11 young adults (aged 22 to 39) with CD was found to have improved markedly 12 and 52 weeks after starting a GFD. This change is probably due to the elevated circulating levels of cytokines associated with systemic inflammation, since a similar "brain fog" phenomenon has been observed in patients with multiple sclerosis, fibromyalgia and chemotherapy exposure.

• Conclusion

Subjective reports of brain fog are supported by objective evidence of mild impairments in cognitive processing and visuospatial memory. Despite the lack of precise mechanistic data, impaired cognitive function in CD is more likely to be related to systemic inflammation than to a specific action of one or more gluten components.

Study Summary

Development and Validation of a Multi-Marker Serum Test for the Assessment of Mucosal Healing in Crohn's Disease Patients

Kelly OB, Silverberg MS, Dulai PD, Boland BS, Vermeire S, Laharie D, Louis E, Bodini G, Savarino E, Kondragunta V, Okada L, Hale M, Li X, Ho J, Kuy C, Huang B, Hester K, Bray K, Mimms L, Jain A, Sandborn WJ, D'Haens G

Congress Abstract - American College of Gastroenterology 2017 - Orlando

https://www.eventscribe.com/2017/wcogacg2017/

• Background

Mucosal healing is now the prime goal in the treatment of Crohn's disease (CD). The gold standard for assessing healing (ileocolonoscopy) is invasive and burdensome for repeated monitoring. A newly developed serological test (based on serum specimens with matching colonoscopy scores) has been proposed as a non-invasive tool for assessing mucosal healing.

• Methods

A logistic regression model was used to validate biomarker levels against endoscopic disease severity scores in CD. The final model (with 13 biomarkers: angiogenesis markers (Ang1, Ang2), cell adhesion proteins (CEACAM1, VCAM1), growth factor signaling components (TGFα), inflammation markers (CRP, SAA1), matrix remodeling markers (MMP-1, -2, -3, -9 and EMMPRIN), and immune modulators (IL7)) produced a mucosal healing index ranging from 0 to 100. The assay was tested on serum collected from adults with CD upon or close to ileocolonoscopy. The model was validated in a prospective cohort of participants in the TAILORIX clinical trial.

• Results

396 patients (males: 49%; mean age: 34; 26% with ileal CD alone, 22% with colonic CD alone, and 52% with both) provided 748 samples. The overall accuracy of the test was 90%. The other performance parameters [95% confidence interval] were accuracy = 90% [87%-93%], sensitivity = 82% [75%-89%], specificity = 94% [91%-97%], positive predictive value = 87% [80%-93%], and negative predictive value = 92% [88%-95%].

• Conclusion

A non-invasive test based on serum biomarkers can be used as a non-invasive surrogate for endoscopic measurement of mucosal healing in patients with CD.

Study Summary

A novel serum test to describe the mucosal healing state by disease location in Crohn's disease patients

Vermeire S, D'Haens G, Hale M, Kondragunta V, Bray K, Jain A, Laharie D

Congress Abstract - American College of Gastroenterology 2017 - Orlando

https://www.eventscribe.com/2017/wcogacg2017/

• Background

Mucosal healing is now the prime goal in the treatment of Crohn's disease (CD). The gold standard for assessing healing (ileocolonoscopy) is invasive and burdensome for repeated monitoring. A newly developed serological test (the Mucosal Healing Index, MHI) based on 748 serum specimens with matching colonoscopy scores) has been proposed as an effective non-invasive tool for assessing mucosal healing.

• Methods

The final model of the serum analysis (with 13 biomarkers: angiogenesis markers (Ang1, Ang2), cell adhesion proteins (CEACAM1, VCAM1), growth factor signaling components (TGFα), inflammation markers (CRP, SAA1), matrix remodeling markers (MMP-1, -2, -3, -9 and EMMPRIN), and immune modulators (IL7)) produces a mucosal healing index ranging from 0 to 100. The investigators sought to assess the test's value in participants in the TAILORIX clinical trial, characterized as having ileal CD alone, colonic CD alone or ileocolonic CD.

• Results

412 longitudinal specimens (96 ileal, 72 colonic, and 244 ileocolonic) were collected from 118 patients with CD (males, 38%; 23% with ileal CD alone, 17% with colonic CD alone, and 60% with both). The test's overall accuracy was 95%, 87% and 90% for ileal, colonic and ileocolonic disease sites, respectively. The MHI's performance values were best for ileal disease and worst for colonic disease (see the Table for values [95% confidence intervals (CI)]).

• Conclusion

A non-invasive serum-based biomarker test has clinical utility in CD, regardless of disease location.

Disease site	Accuracy [95%CI]	Sensitivity [95%CI]	Specificity [95%CI]	Positive predictive value [95%CI]	Negative predictive value [95%CI]
Ileal only (n=96)	95% [88%-99%]	86% [65%-97%]	98% [91%-100%]	95% [73%-99%]	95% [87%-98%]
Ileal and colonic (n=244)	90% [85%-94%]	80% [69%-89%]	95% [90%-98%]	89% [80%-94%]	90% [85%-94%]
Colonic only (n=72)	87% [77%-94%]	89% [67%-99%]	86% [73%-95%]	74% [57%-86%]	95% [84%-99%]
All (n=412)	90% [87%-93%]	82% [75%-89%]	94% [91%-97%]	87% [80%-93%]	92% [88%-95%]

Study Summary

A non-invasive serological test to assess the efficacy of biologic and non-biologic therapies on the mucosal health of patients with Crohn's disease

Dulai P, Boland BS, Vermeire S, D'Haens G, Laharie D, Afif W, Yarur A, Savarino E, Ho J, Hester K, Kondragunta V, Hale M, Jain A and Sandborn W

Congress Abstract - American College of Gastroenterology 2017 - Orlando

https://www.eventscribe.com/2017/wcogacg2017/

• Background

Mucosal healing is now the prime goal in the treatment of Crohn's disease (CD). The gold standard for assessing healing (ileocolonoscopy) is invasive and burdensome for repeated monitoring. A newly developed serological test (based on serum specimens with matching colonoscopy scores) has been proposed as a non-invasive tool for assessing mucosal healing.

• Methods

This was a cross-sectional, multicenter study of a cohort patients with CD, treated (or not) with biologics. The final model of the serum analysis (with 13 biomarkers: angiogenesis markers (Ang1, Ang2), cell adhesion proteins (CEACAM1, VCAM1), growth factor signaling components (TGFα), inflammation markers (CRP, SAA1), matrix remodeling markers (MMP-1, -2, -3, -9 and EMMPRIN), and immune modulators (IL7)) produces a mucosal healing index ranging from 0 to 100. A one way analysis of variance was used to determine differences in mucosal healing index across treatment categories.

• Results

278 patients were studied (males: 43.9%; mean (range) age: 34 (18-88)) and 22 were excluded due to missing data on treatment. About half of the cohort were receiving biologics (adalimumab: 18.3%, infliximab: 15%, anti-integrins: 10.9%, ustekinumab: 6.5%). The remainder were being treated with thiopurines or mesalamine. The overall test accuracy for determining the mucosal severity in this population was 90% (negative predictive value: 89%; positive predictive value: 90%). The mean mucosal healing index was correlated with endoscopic disease severity in individuals treated with biologics and in those not treated with biologics.

• Conclusion

A non-invasive serum-based biomarker test has clinical utility in CD, regardless of treatment type.

Study Summary

Assessing the Variability between Endoscopic Scoring Indices for Evaluation of Crohn's Disease Activity

Laharie D, D'Haens G, Vermeire S, Kondragunta V, Hale M, Parks M, Mimms L, Jain A

Congress Abstract - American College of Gastroenterology 2017 - Orlando

https://www.eventscribe.com/2017/wcogacg2017/

• Background

Mucosal healing is now the prime goal in the treatment of Crohn's disease (CD). Two frequently used measures of mucosal healing are the Crohn's Disease Endoscopic Index of Severity (CDEIS) and Simple Endoscopic Score for Crohn's Disease (SES-CD). The extent to which the CDEIS and SES-CD are related has not been determined in detail.

• Methods

This was a centrally read, prospectively collected analysis of a longitudinal cohort of 118 patients with CD in the TAILORIX clinical trial for whom both CDEIS and SES-CD scores were available (up to 3 per year per patient, 411 data points in all). CDEIS scores were classified as remission <3, mild 3-8, moderate 9-12, and severe >12. For SES-CD, the same groups were respectively defined as <3, 3-6, 7-15, and >15. The two indices were normalized using linear regression.

• Results

Overall agreement between the CDEIS and SES-CD scores for remission, mild, moderate and severe disease severity states was 59% (raw data) or 80% (after normalization with linear regression). For example, 33% of the CDEIS's remission scores were classified as active disease with the SES-CD, and 56% of the CDEIS mild disease classifications corresponded to moderate disease with the SES-CD.

• Conclusion

The CDEIS and SES-CD scores are not equivalent, even after taking the known inter-score offset into account.

Study Summary

Detection of adalimumab and antibodies-to-adalimumab using the Anser® ADA Homogeneous Mobility Shift Assay

Rubin DT, Naik S, Kondragunta V, Rao T, Jain A

Curr Med Res Opin. 2017 May;33(5):837-843

https://www.ncbi.nlm.nih.gov/pubmed/28145781

• Background

A new commercial assay (Anser® ADA, Prometheus Laboratories Inc.) for serum adalimumab (ADL) and antibodies-to-adalimumab (ATA) was launched in 2013 but the use of this assay in clinical practice remains to be characterized in detail.

• Methods

Assays results (anonymous records for commercial Anser® ADA tests) were analyzed (using linear and logistic regression and Wilcoxon's rank sum test) in a real-world cross-sectional population.

• Results

In the two years following launch, 14,239 tests were ordered. Disease monitoring was most common reason for assay prescription (in 46.9% of documented tests). 16.5% of patients were positive for ATAs but around two-third of these individuals had a low ATA titer (1.7-7 U/mL). 87.9% of the ATA-positive patients had serum ADL levels of 4.4 µg/mL or less. In patients (n=2901) on a standard ATA maintenance regimen (40 mg per fortnight), the median serum ADL level was 8.8 µg/mL. Very low ATA titers (1.7-3 U/mL) were associated with 5-fold lower median serum ADL levels ($p<0.0001$). The serum ADL levels decreased further with ATA titers >7 U/mL ($p<0.0001$). High ATA titers were associated with significantly elevated inflammatory marker levels. ADL and ATA levels were inversely correlated. A cut-off of 4.1 µg/mL may distinguish between ATA-positive and ATA-negative patients.

• Conclusion

In this real-world cross-sectional population, serum ADL and ATA levels were inversely correlated, and high ATA titers were associated with elevated inflammatory markers - emphasizing the importance of drug monitoring.

Study Summary

Higher vedolizumab levels are associated with deep remission in patients with Crohn's disease and ulcerative colitis on maintenance therapy with vedolizumab

Yarur A, Bruss A, Jain A, Kondragunta V, Hester K, Luna T, Agrawal D, Patel A, Fox C, Werner S, Naik S, Stein D

Congress Abstract - Digestive Disease Week 2017 - Chicago

http://www.gastrojournal.org/article/S0016-5085(17)31541-X/abstract

• Background

Although the monoclonal antibody vedolizumab (VDZ) is effective in Crohn's disease (CD) and ulcerative colitis (UC), some patients do not respond. The correlation between VDZ pharmacokinetics and response/non-response is not well understood.

• Methods

A cross-sectional, prospective study assessed trough levels of VDZ and anti-VDZ antibodies (ATV) and remission in patients with CD or UC receiving maintenance treatment with VDZ. The Harvey Bradshaw index (HBI) and (when available) the Simple Endoscopic Score-CD (SES-CD) were recorded for patients with CD, and the Mayo Clinical Score (MCS) and (when available) the Mayo Endoscopic Score (MES) were recorded for patients with UC. C-reactive protein (CRP) levels were also recorded. The primary outcome was deep remission (DR), defined as a normal CRP level, a SES-CD score ≤2 and an HBI<5 in CD, and an MES≤1 and an MCS<3 in UC. Steroid-free remission (SFR) was defined as DR plus no steroid treatment for 3 months.

• Results

A total of 56 patients (CD: 41; UC: 15) were included. Twenty (36%) were receiving combination therapy with a thiopurine or methotrexate. 43% and 16% displayed DR and SFR, respectively. ATVs were only detected in 1 patient. The VDZ trough levels were significantly higher in responders than in non-responders (respectively 12.9 vs. 9.4 µg/mL for DR; p=0.008 (Table); and 15 vs. 9.5 µg/mL for SFR [p=0.02]). 5.1µg/mL was the best VDZ cut-off for predicting DR (ρ: 0.713, p=0.03).

	Deep Remission: NO	Deep Remission: Yes
Vedolizumab (Conc.)	9.4 µg/ml	12.9 µg/ml
N	32	24
	P = 0.008	

• Conclusion

Trough levels of VDZ are correlated with effectiveness. VDZ monitoring may be of value in patients with CD or UC.

Table adapted from the original

Study Summary

Higher Vedolizumab Trough Levels Associated with Remission in Inflammatory Bowel Disease (IBD) Patients During Maintenance Therapy

Ungaro R, Jossen J, Phan B, Chefitz E, Jain A, Snehal N, Dubinsky M

Congress Abstract - Digestive Disease Week 2017 - Chicago

http://www.gastrojournal.org/article/S0016-5085(17)31526-3/abstract

• Background

Although the monoclonal antibody vedolizumab (VDZ) is effective in Crohn's disease (CD) and ulcerative colitis (UC), some patients do not respond. The correlation between VDZ pharmacokinetics and response/non-response is not well understood.

• Methods

This was a real-world, cross-sectional study of trough levels of VDZ and anti-VDZ antibodies (ATV) and remission in patients (aged 6 years or over) with CD or UC receiving maintenance treatment. The trough serum VDZ level and the ATV level were measured with a mobility shift assay. Remission was defined as normal C-reactive protein level (<5 mg/L) and a Harvey Bradshaw Index <5 or a Partial Mayo Score of 0 or 1.

• Results

113 patients (50 with CD and 63 with UC) were included (mean ± standard deviation (SD) age: 33.3 ± 15.1; males: 54%; Caucasians: 87%; mean disease duration: 12.3 years; mean number of VDZ infusions: 7.9 ±4.4; median (range) VDZ level: 11 (1.4–100.1 µg/mL). Median [interquartile range (IQR)] levels of VDZ were higher in patients in remission (12.1 [9.5–19.9] µg/mL) than in those not in remission (9.6 [IQR 5.7–16.9] µg/mL; p=0.01); this was also true for patients with UC (median: 14.3 versus 9.8 µg/mL; p=0.04). A VDZ level above the median (11 µg/mL) was associated with a greater likelihood of being in remission (odds ratio [95% confidence interval = 2.65 [1.24–5.66]). Immunomodulator use did not influence these results. ATVs were found in only 3.5% of patients.

• Conclusions

During VDZ maintenance therapy, drug levels were significantly higher in patients in remission.

Study Summary

The NutriQoL® questionnaire for assessing health-related quality of life (HRQoL) in patients with home enteral nutrition (HEN): validation and first results

Apezetxea A, Carrillo L, Casanueva F, Cuerda C, Cuesta F, Irles JA, Virgili MN, Layola M, Lizán L

Nutr Hosp. 2016; 33(6):1260-1267

https://www.ncbi.nlm.nih.gov/pubmed/28000451

• Background

In patients receiving enteral nutrition (EN) in a homecare setting, health-related quality of life (HRQoL) is a guide to overall health status.

• Methods

In a prospective, observational, multicenter study, the specific NutriQoL® questionnaire was used to evaluate HRQoL in patients receiving EN at home. The NutriQoL® questionnaire's psychometric properties were assessed. Other HRQoL tools were also administered.

• Results

The study featured 140 patients from a variety of disease/treatment scenarios, primarily cancer (58.6%) and then malabsorption and related disorders (27.1%) and neurological disorders (13.6%). The enteral nutrition was primarily given orally (54.3%, vs. 31.4% via oral ostomy and 12.1% via a nasoenteric tube) as a supplement (61.4%). The mean ± HRQoL score was variously 14.98±14.86 with the NutriQoL® was 53±0.25 with the EQ-5D tariff, 54.15±20.64 with the EQ-5D visual analog scale, and 23.32±5.66 with COOP/WONCA charts. The NutriQoL® was found to be reliable (intraclass correlation coefficient (ICC) [95%CI]=0.88 [0.80-0.93]; Cronbach's alpha: 0.77 and 0.83 on the first and second visits, respectively) and valid (significant Rho) but was not highly sensitive to change (effect size=0.23). The NutriQoL® could be completed as a self-questionnaire or by a caregiver (intraclass ICC=0.82). According to the NutriQoL®, the patients' HRQoL was highest for oral administration [19.54 ± 13.23)], relative to all the other administration routes. The patients' HRQoL was also higher for EN given as a supplement [19.33 ±13.73)] instead of as the sole source of nutrition [8.18 ± 14.23)].

• Conclusion

The NutriQoL® questionnaire its a valid and reliable tool for measuring HRQoL in patients receiving EN at home. Patients HRQoL was higher for EN given as a supplement instead of as a sole source of nutrition.

Study Summary

Preferences for the attributes of home enteral nutrition (HEN) in Spain. Do caregivers know their patients' preferences?

Olveira G, Martínez MA, Fernández B, Ferrer M, Virgili MN, Vega B, Blanco M, Layola M, Lizán L, Aceituno S

Nutr Hosp. 2017 Oct 24;34(5):1013-1023

https://www.ncbi.nlm.nih.gov/pubmed/29130697

• Background

Home enteral nutrition (HEN) can improve a patient's quality of life. In many cases, HEN requires the patient to be assisted by a caregiver. The extent to which caregivers know their patients' priorities may influence the benefit derived from HEN.

• Methods

A cross-sectional observational study in Spain assessed patients' reports of the most important features of HEN, using a set of eight choice scenarios generated from six attributes with two levels. An ad hoc questionnaire on the importance and satisfaction with HEN was also administered. The relative importance of each attribute and the level of agreement between patients and caregivers were estimated.

• Results

A total of 148 patients were included in the study, and caregiver data were available for 77 of the patients. The most important features of HEN were stated as ability to adapt to comorbidities (33%), tolerability (33%), the nutrient and calorie content (26%), and the characteristics of the packaging (8%). The level of patient-caregiver agreement was moderate to good, and patients were very satisfied with the assistance provided by caregivers.

• Conclusion

Patients' top preferences for a HEN product are adaptability, tolerance, nutritional content, and easy-to-handle packaging. Caregivers are aware of their patients' preferences.

Study Summary

Prevalence and Management of Enteral Nutrition Intolerance in the Non-ICU Setting in Canada

Hopkins B, Donnelly M, Davis B, Madill J

Canad J Clin Nutr. 2017; 5 (2): 82-101

http://globalscienceheritage.org/downloads/prevalence-and-management-of-enteral-nutrition-intolerance-in-the-non-icu-setting-in-canada/

• Background

Enteral nutrition intolerance (ENI) interferes with nutritional targets and is associated with dehydration and poor patient quality of life. Although ENI in intensive care units (ICUs) is well studied, data on this problem outside the ICU are scarce.

• Methods

An online survey in Canada collected data on the prevalence and management of ENI in non-ICU settings. The participants (recruited via convenience sampling) were registered dietitians working in acute-care (AC), long-term care (LTC) or homecare (HC) settings.

• Results

A total of 240 registered dietitians completed the survey (100 for AC; 80 for LTC and 60 for HC) and provided information on a total of 5611 patients managed in the previous three months. Between 35% and 66% of these patients had one or more signs of ENI. Diarrhea was the most prevalent sign in all care settings (27% for AC, 15% for LTC, and 20% for HC; p=0.001). Reflux, fullness, nausea and bloating were more frequent in HC patients than in AC and LTC patients. In all settings, the most frequent management approach was to reduce the volume of enteral nutrition formula.

• Conclusion

ENI is common outside the ICU. Diarrhea is the most prevalent problem in all care settings, while reflux, nausea and bloating are more frequent in HC patients.

Article Summary

Natural Bioactive Food Components for Improving Enteral Tube Feeding Tolerance in Adult Clinical Populations

Kuchnia AJ, Conlon B, Greenberg N

Review article: Nutr Clin Pract. 2017 Aug 1:884533617722164

https://www.ncbi.nlm.nih.gov/pubmed/28820648

• Background

Enteral nutrition intolerance (ENI, usually nausea, diarrhea or constipation) limits the efficacy of enteral nutrition. Some whole foods have been investigated as a means of reducing ENI and promoting enteral nutrition in chronic and critical illness.

• Methods

A literature search for full-text, English-language records of randomized controlled trials listed in PubMed and Scopus®.

• Results

The review focused on five whole foods and analyzed 2 trials for rhubarb (targeting constipation, gastroparesis and reflux), 7 for ginger (nausea and vomiting), 5 for banana (diarrhea), 6 for peppermint oil (gastrointestinal pain and spasms), and 4 for curcumin (inflammation). The anthraquinone glycosides in rhubarb increase gastric motility but caution is required (due to oxalate levels) in a context of stone formation. Ginger compounds may antagonize the serotonin type 3 receptor; ginger is a promising treatment for nausea and vomiting, and few adverse events have been reported. The high resistant starch content is though to give banana its antidiarrheal effects. When added to an enteral regimen, banana flakes are effective and should be considered for the management in critically ill patients. The antispasmodic effects of peppermint oil are attributed to monoterpenes and sesquiterpenes; several recent reviews support the use of enteric-coated peppermint oil in irritable bowel syndrome. The polyphenols in curcumin appear to produce small but not always statistically significant benefits in inflammatory bowel disease.

• Conclusion

The whole foods are of clinical value but formulations, format and dose need to be considered for optimal activity.

Study Summary

Nutrition and physical activity in the prevention and treatment of sarcopenia: systematic review

Beaudart C, Dawson A, Shaw SC, Harvey NC, Kanis JA, Binkley N, Reginster JY, Chapurlat R, Chan DC, Bruyère O, Rizzoli R, Cooper C, Dennison EM; IOF-ESCEO Sarcopenia Working Group

Osteoporos Int. 2017 Jun;28(6):1817-1833

https://www.ncbi.nlm.nih.gov/pubmed/28251287

• Background

This is an update of Denison et al.'s 2013 analysis of 17 randomized controlled trials (RCTs) assessing the effect of combined exercise and nutrition intervention on muscle mass, muscle strength or physical performance in older adults.

• Methods

Two independent reviewers searched and extracted MEDLINE® and EMBASE® databases for RCTs combining exercise and nutritional intervention in adults aged 60 and over.

• Results

A total of 37 RCTs were reviewed. The dietary supplements varied markedly: proteins, essential amino acids, creatine, β-hydroxy-β-methylbuthyrate, vitamin D, multinutrients, and other supplements. Muscle mass increased with exercise in 79% of the documented studies but an additional effect of nutritional intervention was only found in 23.5% of documented studies. Similarly, muscle strength increased in 82.8% of studies but an additional effect of nutritional intervention was only found in 22.8% of documented studies. Lastly, enhanced physical performance (the most marked effect of the exercise intervention) was reported in 92.8% of documented studies but an additional effect of nutritional intervention was only found in 14.3% documented studies.

• Conclusion

Physical exercise has a positive impact on muscle mass and strength function physical performance in healthy older adults but an additional effect of dietary supplementation may be limited to certain patient populations and nutritional formulations.

Article Summary

Current Concepts and Unresolved Questions in Dietary Protein Requirements and Supplements in Adults

Phillips SM

Review article: Front Nutr. 2017 May 8;4:13
https://www.ncbi.nlm.nih.gov/pubmed/28534027

• Background

The recommended dietary allowance (RDA) for subpopulations of patients or older adults has not been defined.

• Methods

A literature review/opinion article.

• Results

Based on the nitrogen balance, the RDA for healthy adults has long been set to 0.80 g/kg/day. However, an RDA of 1–1.2 g/kg/day has been suggested, particularly in the elderly. Digestibility (as estimated by the Digestible Indispensable Amino Acid Score and the Protein Digestibility-Corrected Amino Acid Score) is a modifying parameter of protein dose. Sarcopenic muscle loss proceeds at ~0.8%/year, and strength is lost at a rate of 1–3%/year; so older adults (and chronically ill patients but not acutely ill patients) appear to have a greater requirement for leucine or leucine-containing protein, in order to stimulate muscle protein synthesis and attenuate the loss of muscle mass and function. Protein levels of 2–2.5 g/kg/day have been recommended for critically ill patients. With regard to protein overload, the current guidelines for chronic kidney disease suggest that lower protein levels (as low as 0.3–0.9 g/kg/day, depending on the disease stage) are advisable. Creatine and beta-hydroxy-beta-methylbutyrate (β-HMB) have been most intensively studied as adjunctive ingredients. In meta-analyses, creatine has been shown to enhance exercise-induced gains in lean body mass and muscle strength/function. In contrast, β-HMB appears to have trivial effects on muscle mass and none on muscle function.

• Conclusion

There is a good theoretical framework for higher protein intake in critical illness that may differ from that in acute illness.

Article Summary

Medical nutrition terminology and regulations in the United States and European Union: a scoping review

Volger S, Freyer K, Pitter JG, Molsen E, Cooblall C, Evers S, Hiligsmann M, Danel A, Aggarwal B, Seyhun O, Ofili T, Goates S, Partridge J, Laplante S

Congress Poster (PHP190) - ISPOR US 2017 - Boston

https://www.ispor.org/ISPOR_Med_Nutrition_Terminology_and_Regulations_Poster.pdf

• Background

Standardized terms and definitions are needed for accurate health economics evaluations of parenteral nutrition (subject to the legislation on pharmaceuticals) and enteral nutrition (subject to the legislation on foods).

• Methods

The ISPOR Nutrition Economics Special Interest Group systematically searched the scientific literature published from January 2000 to April 2017 and professional and regulatory websites for terms related to medical nutrition (i.e. both parenteral and enteral nutrition). Two-person teams independently screened and extracted the data in a two-step process. The output was a scoping review of how terms in medical nutrition are defined and how regulations are applied in the USA and the European Union.

• Results

1909 records were identified (1,687 scientific publications and 222 website records) and 458 were reviewed. 67% of the articles (in 13 primary disease areas, according to ICD-10 codes) cited medical nutrition terms, and 22% of these gave a definition of one or more terms. Malnutrition was the most frequently mentioned term (in 88 of the 458 articles, 19.2%). Fewer than 5% of the articles cited regulations in medical nutrition. There were few health economics studies of medical nutrition, although the period 2015-2017 has witnessed a significant increase.

• Conclusion

Terms in medical nutrition are not used consistently; there is a need for consensus definitions.

Study Summary

Development and validation of a specific questionnaire to assess health-related quality of life in patients with home enteral nutrition: NutriQoL® development

Cuerda MC, Apezetxea A, Carrillo L, Casanueva F, Cuesta F, Irles JA, Virgili MN, Layola M, Lizan L

Patient Prefer Adherence. 2016 Nov 4;10:2289-2296

https://www.ncbi.nlm.nih.gov/pubmed/27853360

• Background

Home enteral nutrition (HEN) is indicated in patients who are unable to meet their nutritional requirements with oral nutrition. Generic tools for measuring health-related quality of life (HRQoL) in patients receiving HEN may not be sensitive enough.

• Methods

The new NutriQoL® HRQoL questionnaire for patients receiving HEN was developed following a literature review, an expert focus groups, semi-structured patient interviews, validity and feasibility assessments, and a Rasch analysis of 141 patients and 24 caregivers.

• Results

17 out of 52 initial items were selected for the NutriQoL®. The selected items were acceptable in terms of frequency, importance, and clarity. A visual analog scale for global HRQoL was also implemented. NutriQoL® was independent of the indication for HEN and the administration route.

• Conclusion

The NutriQoL® HRQoL questionnaire appears to be of value in patients receiving HEN and will be validated in routine clinical practice to ensure validity, reliability and sensitivity to changes in health status.

Study Summary

Reliability and Responsiveness of NutriQoL Questionnaire

Cuerda MC, Apezetxea A, Carrillo L, Casanueva F, Cuesta F, Irles JA, Virgili MN, Layola M, Lizán L

Adv Ther. 2016 Oct;33(10):1728-1739

https://www.ncbi.nlm.nih.gov/pubmed/27469466

• Background

The NutriQoL® health-related quality-of-life (HRQoL) questionnaire assesses patients receiving home enteral nutrition (HEN). The results are independent of the indication for HEN and the administration route.

• Methods

To assess the NutriQoL®'s test-retest reliability, internal consistency and responsiveness to change, the questionnaire was administered several times in two cohorts of adult patients with HEN and their primary caregivers. The minimal clinically important difference was also estimated.

• Results

54 and 86 patients receiving HEN were recruited into the reliability and responsiveness cohort, respectively, and 35 caregivers were recruited into the inter-observer reliability cohort. Intra-class correlation coefficient values >0.75 confirmed the NutriQoL®'s reproducibility for the "physical functioning and activities of daily living" and "social life" domain scores and the total score. There was good internal consistency. For the overall NutriQoL® score, the level of agreement between the caregiver and the patient was excellent. The mean (standard deviation) change in the NutriQoL® score for a minimal change was 0.63 (11.51) points.

• Conclusion

The NutriQoL® HRQoL questionnaire is reliable and sensitive to changes in health status in patients receiving HEN. The instrument's full extent responsiveness must be further assessed.

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