## Update: 2019 American Diabetes Association Nutrition Consensus Report

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#### Session Objectives

- Discuss eating patterns which may be most effective for the management of diabetes
- Review current recommendations for vitamin, mineral and herbal supplements for people with diabetes
- Discuss energy balance strategies for the management of diabetes

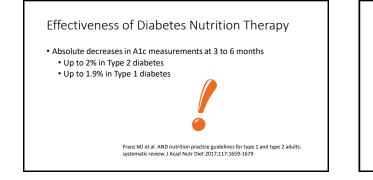
#### ADA Nutrition Consensus Report Committee Members

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- Michelle Dennison
- Christopher D. Gardner
- W. Timothy Garvey
   Ka Hei Karen Lau
- Janice MacLeod
- Joanna Mitri
- Raquel F. Pereira
- Kelly Rawlings
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- Laura Saslow
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### ADA Nutrition Consensus Report

- Published online last week, to be published in May 2019 Diabetes
   Care journal
- Study inclusion criteria:
  - Only studies including adult subjects with diabetes or prediabetes
  - RCTs, systematic reviews, meta-analyses of RCTs
  - 10 subjects per arm of study
  - Retention rate of at least 50%





#### Macronutrient review for diabetes

- What is the usual macronutrient intake of Americans?
- There is no ideal mix of macronutrients for diabetes management
   Macronutrient distribution should be based on individual assessment of
   current eating patterns, preferences and metabolic goals
- Key strategy
  - Provide guidance on self-monitoring of carbohydrate intake to optimize meal timing and food choices, and
  - Guide medication and physical activity recommendations

### Carbohydrate

- Key strategy for optimizing glycemic control should include
  - · Assessment of dietary intake
  - Individualized guidance on monitoring carbohydrate intake
  - Guide medication and physical activity recommendations in relation to carbohydrate intake

# Is using an Insulin-to-Carbohydrate Ratio for type 2 diabetes necessary?

- No RCTs to demonstrate necessity
- 2013 RCT reported similar improvements in A1c when using a simplified algorithm to increase mealtime insulin doses compared to using an ICR.

Mealtime dose	Avg pre-meal BG below target over past week	Avg pre-meal BG above target over past week
<u>&lt;</u> 10 units	- 1 unit	+ 1 unit
11-19 units	- 2 units	+ 2 units
<u>&gt;</u> 20 units	- 3 units	+ 3 units
	Bergenst	al RM et al. Diabetes Care 2008

# Do humans require 130 grams of carbohydrate per day for optimal health?

- Dietary allowance is 130 g per day, calculations based on brain's requirement for glucose
- BUT this energy requirement can be fulfilled by glycogenolysis, gluconeogenesis and/or ketogenesis

#### **Glycemic Index**

- 2 systematic reviews (2017, 2018) reported no significant impact on A1c and mixed results on fasting glucose
- Studies have used varying definitions of high and low glycemic index foods

Franz MJ et al. J Acad Nutr Diet. 2017;117:1659-1679 Vaga-Lopez S et al, Nutrients. 2018;10:E1361

#### Fiber

- A few studies have shown modest reduction in A1c (-0.2 to -0.3%) with fiber intake greater than 50 g per day
- Need to consider risk of flatulence, bloating diarrhea with this level of fiber intake
- DGA 2015-2020 fiber recommendation is appropriate
  - 14 g per 1000 kcal
  - Half of grain consumption being whole intact grains
  - Other food sources include non-starchy vegetables, avocadoes, fruits and berries



Should grams of fiber and sugar alcohols be subtracted from grams of total carbohydrate?

#### Protein

- 2013 meta-analysis reported that high-protein eating plan (25 to 32% of total energy vs. 15 to 20%) resulted in
  - 2 kg greater weight loss
  - 0.5% greater improvement in A1c
  - No statistically significant improvement in fasting glucose, lipids, blood pressure

Dong J-Y et al. Br J Nutr 2013;110:781-789

#### Dietary Fat and Cholesterol (non-CVD)

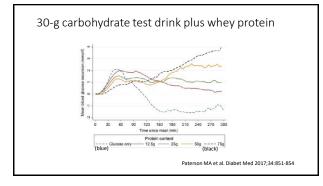
- National Academy of Medicine recommendation: 20 to 35% of total calorie intake for individuals without diabetes
- However, diabetes eating pattern studies with higher levels of fat have demonstrated greater improvements in glycemia, HDL-C, triglycerides compared with lower fat diets
- Type 2 diabetes: replacing high carbohydrate foods with lowercarbohydrate foods may improve glycemia, triglycerides, HLD-C
   Emphasizing foods higher in unsaturated fats in place of saturated fats may improve LDL-C
- Exact recommendations for dietary cholesterol for people with diabetes are not known

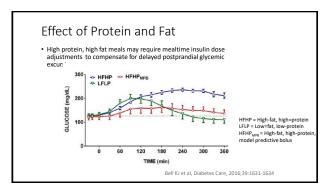
# Fat Recommendations for Those With or At Risk for Cardiovascular Disease

- In general, replacing saturated fat with unsaturated fats reduces total cholesterol and LDL-C
- Recent meta-analyses and systematic reviews reported improved body weight, glycemic measures and CVD risk factors with eating plans high in monounsaturated fat
- Foods rich in omega-3 fatty acids recommended
   Omega-3 supplements may reduce CV events
- Sodium intake of 2300 mg per day is recommended
   Less than 2300 mg per day should be considered only on an individual basis due to cost, availability, preferences and palatibility

# Potential Effect of Protein and Fat on Blood Glucose

- Individuals taking mealtime insulin may need to adjust mealtime dose when consuming more protein and fat than usual
- 14 recent type 1 diabetes studies reveal increases in post-meal blood glucose levels with increased amounts of protein and/or fat
- Glucose response differs among individuals
- BG increases seen with intake of >40 g fat or >25 g protein





#### Protein and Chronic Kidney Disease

- Restricting protein below RDA (0.8 g per kg) does not alter course of glomerular filtration rate decline in individuals with diabetic kidney disease
- But what if individual is following a high protein, low carbohydrate diet?
  - Current ADA 2019 Standards of Care state that protein intake >1.3 g per kg body weight have been associated with increased albuminuria, more rapid kidney function loss and CVD mortality and therefore should be avoided
  - Evidence for this recommendation is <u>observational</u> data from the Nurses' Health Study
  - Nutrition Consensus Report: Evidence does *not* suggest protein restriction below average protein intake for those with CKD

#### **Energy Balance**

- Type 2 diabetes
  - 5% loss to achieve clinical benefits
  - 15% for more optimal benefits, when needed and can be safely accomplished
  - Medication-assisted weight loss can be considered
    Metabolic surgery should be considered in select individuals
- Prediabetes
  - 7-10% to prevent progression to type 2 diabetes
- Individuals should be evaluated for disordered eating and nutrition therapy should accommodate these disorders

What eating plan should we be recommending for diabetes?

#### Eating Patterns Reviewed

- For type 2 diabetes, prediabetes, type 1 diabetes
  - Low-fat <30% of total kcal</li>
     Mediterranean olive oil, nuts/seeds, fruits, vegetables, beans, fish,
  - DASH (Dietary Approaches to Stop Hypertension) rich in
  - DASH (Dietary Approaches to Stop Hypertension) rich in fruits, vegetables, whole grains, low-fat dairy products, and low in fat, refined grains, and sweets; max sodium of 2,400 mg per day
  - Paleo lean meat, fish, fruits, vegetables, root vegetables, eggs, and nuts; avoids grains, dairy, salt, refined fats, sugars
  - Very Low Fat (Ornish or Pritikin) very low-fat (10% of kcal), exercise, stress management
  - Vegetarian or vegan
  - Low-carbohydrate 26 to 40% of calories from CHO
  - Very low-carbohydrate 20 to 50 g CHO/day or <26% calories from</li>

#### Remission of type 2 diabetes?

- Standard of care rarely leads to type 2 diabetes remission (HbA1c < 6.5% and no glucose-lowering medications or just metformin)
- In 123,000 patients over 7 years, only about 3% achieved remission in a community-based study

Karter AJ et al. Diabetes Care 2014;37:3188-3195

### DiRECT Trial

- 306 subjects with T2 DM, 49 general practice clinics
- 20 to 65 years old, diabetes duration < 6 years, BMI 27 to 45 kg.m<sup>2</sup>
- 12 month intervention:
- Stop diabetes and BP meds
- 825 to 853 kcal formula diet for 3 to 5 months
- Stepped food re-introduction
- Structured support (monthly visits)
- Control: Best practice care
- Goal outcomes:
  - 15 kg weight loss
  - Diabetes remission (A1c <6.5% after 2 months off all diabetes meds)

#### DiRECT Plan and Stepped Food Re-introduction

- Initial weight loss period: 12 weeks or 20 kg weight loss (plus fiber
- supplement) • 810 to 833 kcal weight loss liquid diet plus fiber supplement
- Appointments weekly, then every 2 weeks
- 360 to 400 kcal meal introduced every 2 weeks as weight loss shakes reduced
- Weight-loss maintenance stage: 34 weeks
  - All food
  - 500 to 600 kcal deficit
  - Approximately 30% energy from fat; upper limit 2500 kcal/day
  - 120 mg orlistat (optional)Monthly appointments, telephone support offered

### **DiRECT Trial Results**

- At 12 months, 24% of participants in intervention group lost 15 kg or more, none in the control group
- Diabetes remission was achieved in 46% of intervention group and 4% in control group
  Remission varied with weight loss in the entire study population (86%)
- in participants who lost 15 kg or more; 73% in those who lost 10 kg or more)
- 68% stopped BP medications
- QOL improved in intervention group, decreased in control group

Conclusion: Remission of type 2 diabetes is a practical target for primary care.

Lean MEJ et al. Lancet 2018;391:541-551

Eating Patterns for Type 2 Diabetes Summary

- Mediterranean: Reduced A1c, weight, triglycerides; reduced risk of CV events; reduced Db risk
- Vegetarian/vegan: Reduced A1c, weight, LDL-C and non-HDL-C; reduced Db risk
- Low-fat: Reduced weight; reduced Db risk
- Very low-fat (Ornish/Pritikin): Reduced weight
- Low-carbohydrate: Reduced A1c, weight, BP, triglycerides, increased HDL-C

# Eating Patterns for Type 2 Diabetes Summary, cont.

- Very low-carbohydrate: Reduced A1c, weight, triglycerides, BP; reduced need for anti-glycemic medications compared to higher carbohydrate diets
- DASH: Reduced weight, BP, reduced diabetes risk
- Few RCTs with comparison other than low-fat eating plans. A1c changes:
  - 24 mo trial with 25 people, low-carb -0.9% vs. Mediterranean -0.5% (Shai I et al. N Engl J Med 2008; 359:229-241)
  - 12 mo trial with 194 people, low-carb Med -2.0%, traditional Med -1.8%, low-fat -1.6% (low-carb Med also higher HDL, lower trigly) (Elhayany A et al. Diabetes Obes Metab. 2010 Mar;12(3):204-209)



### Vegetarian/Vegan Eating Plans

- 6 studies ranging from 12 to 74 weeks
- 2 meta-analyses
  - $\bullet$  A1c reduction of 0.3 to 0.4%
  - Larger meta-analysis reported
  - 2 kg weight reduction
  - Decreased waist circumference
  - Decreased LDL-C
  - No significant effect on fasting insulin, HDL-C, triglycerides, blood pressure

Yokoyama Y et al. Cardiovasc DiagnTher 2014;4:373-382 Viguiliouk E et al. Clin Nutr Jun 2018; 10.1016/j.clnu.2018.05.032

# Low-Carbohydrate and VLC and Type 2 DM: 3 Meta-analyses

- Carbohydrate-restricted diets (<45% , especially <25% energy) produced greater reductions in A1c at 3 and 6 months, but no difference at 12 and 24 months  $^{\rm 1}$
- Compared to low-fat diets (<30% energy), LC diet (<40% energy) improved A1c more (up to 6 months), improved triglycerides, increased HDL-C, lowered blood pressure and reduced need for diabetes medications (varying time lengths)<sup>2</sup>
- $\bullet$  The greater the carbohydrate restriction, the greater the reduction in A1c up to 1 year (-0.34%); reduction in A1c was similar at 1 year and after  $^3$

<sup>1</sup>Sainsbury E te al. Diab Res Clin Pract 2018;139:239-252 <sup>2</sup>vanZuren EJ et al. Am J Clin Nutr 2018;108:300-331 <sup>3</sup> Snorgaard O et al. BMJ Open Diabetes Res Care 2017;5:e000354 "This analysis does not support the long-held preference for low-fat diets as the default intervention for T2D. Instead the results suggest that if it fits the patients' preferences, restriction of carbohydrate may be slightly better, although the clinical benefits are uncertain."

- vanZuren et al

### 2019 Nutrition Consensus Report

"For select adults with type 2 diabetes not meeting glycemic targets or where reducing antiglycemic medications is a priority, reducing overall carbohydrate intake wit low- or very low-carbohydrate eating plans is a viable approach."

#### Type 1 Diabetes Summary

Evidence suggests that a very low-carbohydrate diet *may* have health benefits for adults with type 1 diabetes, but clinical trials of sufficient **size and duration** are needed for this and all the eating patterns.

#### Type 1 Diabetes: Very Low-carbohydrate

- Randomized crossover trial of VLC (47 g CHO) vs higher carbohydrate (225 g CHO), 10 subjects for 1 week each. On VLC diet: less glycemic variability, more time in euglycemia, less time in hypoglycemia, required less insulin
- Single-arm, 4 year trial, 48 subjects, goal 75 g CHO per day: A1c was lower and HDL-C was still higher than at baseline
- Survey of 316 people with type 1 diabetes or the parents of children with type 1 diabetes, mean HbA1c was in the normal range (5.7%), with a low daily insulin requirement\*

Ranjan A et al. Diab Obes Metab. 2017;19:1479-1484 Nielsen JV et al. Diabetol Metab Syndr. 2012;4:23 \*Lennerz BS. Pediatrics. 2018;141(6):e20173349 (not in consensus report)

# Lennerz Type 1 VLCD Survey (NOT in Consensus Statement)

- Reported mean daily CHO intake 36 + 15 g per day
- 27% did not discuss VLCD with diabetes care providers
- 49% agreed or strongly agreed that diabetes care providers were supportive of VLCD
- Did not report VLCD to providers because of:
  - Disagreement on diet approach
  - Perceived provider disinterest or unfamiliarity
    Desire to avoid conflicts
  - Fear of being accused of child abuse (parents of T1 children)

Lennerz BS. Pediatrics. 2018;141(6):e20173349

#### Until there is more evidence...

Focus on key factors that are common among eating patterns:

- Emphasize non-starch vegetables
- Minimize added sugars and refined grains
- Choose whole foods over highly processed foods to the extent possible

#### Micronutrients, Herbal Supplements

- No evidence to recommend multivitamins or mineral supplements without underlying deficiency
- No evidence to support use of any herbal supplement or vitamin D or chromium supplements to improve glycemia

#### Personalized Nutrition

- Inadequate evidence to recommend the use of personalized nutrition guidance based on genetic, metabolomics and microbiome information
- Wide variations in the markers used for predicting outcomes and the populations that have been studied
- Further research is needed

### Future Research

- Longer, larger studies
- Study various eating patterns against on another
- Control for supplementary advice (physical activity, stress reduction, smoking cessation, etc)
- Examine impact of weight loss from an eating pattern on other outcomes (glycemia, lipids, blood pressure)il
- Tailor MNT and DSMES to difference racial/ethnic and socioeconomic groups
- · Different delivery methods
- Ongoing cost-effectiveness studies to support coverage of service

