Which foods are displaced in the diets of adults with type 2 diabetes with the inclusion of eggs in their diets? A randomized, controlled, crossover trial

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ABSTRACT

Background The inclusion or exclusion of specific foods from the overall diet inevitably affects other food choices, and this matter is routinely neglected in dietary guidance and nutritional epidemiology. We examined how the inclusion of eggs in the diets of type 2 diabetics affected dietary pattern.

Methods Randomized, controlled, single-blind, crossover trial of 34 adults (mean age 64.5 years; 14 women, 20 men) with type 2 diabetes assigned to one of two possible sequence permutations of two different 12-week treatments (two eggs/day or egg exclusion), with 6-week washout periods. For the egg inclusion phase, participants received advice from a dietitian on how to preserve an isocaloric condition relative to the egg exclusion phase. To assess changes in dietary pattern in the diets of our study participants, we analyzed the 12 components of the 2010 Healthy Eating Index.

Results The inclusion of eggs was associated with reduced consumption of refined grains nearing statistical significance (-0.7 ± 3.4 vs 0.7 ± 2.2; p=0.0530). The consumption of total protein foods significantly increased from baseline (0.3 ± 0.7; p=0.0153) with the inclusion of eggs for 12 weeks, while the consumption of dairy products significantly decreased with the exclusion of eggs from their diets (-1.3 ± 2.9; p=0.0188).

Conclusions Eggs in the diets of type 2 diabetics may lead to increased consumption of some healthful foods and reduced consumption of some less healthful foods.

Trial registration number NCT02052037; Post-results.

Significance of this study

What is already known about this subject?

► Foods displaced from ad libitum diets while accommodating for the inclusion of a tested food are routinely not investigated as part of clinical research studies. Few dietary intervention studies have included this type of investigation as part of their study protocol design.
► We examined the foods displaced from the diets with type 2 diabetes while including eggs as part of their otherwise ad libitum diets.

What are the new findings?

► The inclusion of eggs in the diets of type 2 diabetics may improve protein foods consumption.
► The inclusion of eggs in the diets of type 2 diabetics may reduce consumption of refined grains.

How might these results change the focus of research or clinical practice?

► The results of this study may serve as guidance to nutrition researchers and professionals who provide dietary guidance to people with type 2 diabetes on foods to displace when including eggs in their diets.

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BACKGROUND

Diabetes is a public health problem of epidemic proportions. According to the 2014 National Diabetes Statistics Report, 29.1 million people, or 9% of the US population, are estimated to have diabetes, of which 21.0 million people are diagnosed.[1] About 86 million people, or one in three people in the USA, are estimated to have pre-diabetes,[1] yet 9 out 10 people with pre-diabetes are unaware that they have this condition.[1] Of the people who have pre-diabetes, 15%–30% are likely to develop type 2 diabetes with 5 years.[1]

The risk of death in individuals with diabetes is more than 50% higher than for adults without diabetes. Type 2 diabetes accounts for about 90%–95% of all diagnosed cases of diabetes. Diabetes is the seventh leading cause of death in the USA. Diabetes complications include cardiovascular disease (CVD), stroke, hypertension, blindness, kidney disease, nervous system damage, limb amputations, and biochemical imbalances that can cause acute life-threatening events. Rates of cardiovascular mortality are 2–4 times higher among adults with diabetes than among those without diabetes.[2]

There is no cure for type 2 diabetes. The cornerstone of the management and prevention of type 2 diabetes is lifestyle intervention.[2]

Previous studies have shown that a reduction of 5%–7% in body weight can lead to a significant improvement in insulin sensitivity, glycemic control, reduced medication use, and reduced risk of developing type 2 diabetes.[3–6] Low glycemic index foods are typically recommended for patients with type 2 diabetes or at risk for type 2 diabetes. Diets with a low glycemic load have been reported to improve serum lipid profiles, reduce C reactive protein (CRP) levels, and aid in weight control. In cross-sectional studies, they have been associated with higher levels of high-density lipoprotein cholesterol, with reduced CRP concentrations, and, in cohort studies, with decreased risk of developing diabetes and CVD.[7]

In a previous publication,[8] we demonstrated that the inclusion of eggs in the diets of adults with type 2 diabetes led to improved anthropometric measures, but did not describe the foods displaced with the inclusion of eggs in their diets. This report further elaborates the findings from that study by evaluating the foods displaced from the diets of these adults with type 2 diabetes with the inclusion of eggs.

METHODS
Design
This is a randomized, single-blind crossover trial designed with a 4-week run-in period and two treatment assignments to compare the effects of 12 weeks of daily inclusion or daily exclusion of eggs on dietary pattern in adults with type 2 diabetes. After a 4-week run-period of ad libitum diet, participants were randomized and then underwent repeated measures following inclusion of 10–14 eggs per week or egg exclusion for 3 months in their diets in random sequence (ie, one of two sequence permutations), with a 6week washout between treatments. The investigators were blinded to the treatment assignments, while the study participants were not. Details of the study design—including inclusion/exclusion criteria, and randomization process—are presented in our previous report.[8] This study was approved by the Griffin Hospital Institutional Review Board.

Egg inclusion phase
Participants met with a registered dietitian and received instructions for including two eggs per day (10–14 eggs/week) in their diets, while preserving an isocaloric condition relative to the egg exclusion phase. The study dietitian provided individualized guidance to participants on how to make room for eggs in their diets, while giving them latitude in determining how to adjust for the extra calories from the eggs, to better approximate real-world conditions.

Egg exclusion phase
Participants also met with the dietitian and receive relevant meal planning guidance and instructions to avoid eggs and specific egg-containing products.

During both intervention phases, study participants were advised to eat to their usual state of fullness, and dietary monitoring and weighing were conducted to ensure that an isocaloric condition was maintained.

Outcome measure
We tracked variation in dietary patterns over the course of the study by asking study participants to provide information on the foods and beverages that they consumed by completing 24 hours recalls using a web-based Automated Self-Administered 24 hours Recall (ASA24) (http://riskfactor.cancer.gov/tools/instruments/asa24/). Three 24 hours recalls (ie, for two weekdays and one weekend day) were collected at each timepoint. The average of the 3-day recalls at each timepoint was used to assess diet quality.

The food groups were assessed using the subscale of the Healthy Eating Index (HEI) 2010. The HEI is a measure of the diet quality, independent of quantity, which is used to assess compliance with the U.S. Dietary Guidelines for Americans and monitor changes in dietary patterns. The HEI is a scoring metric that is used to determine the quality of a given dietary pattern, set of foods, or menu. There are 12 components in the HEI–2010. All of the key Dietary Guidelines food choice recommendations that relate to diet quality are reflected in the HEI–2010's 12 components. Nine of the components focus on adequacy (dietary components to increase), and three focus on moderation (dietary components to decrease). The performance of the HEI–2010 has been evaluated through an assessment of its content validity, construct validity, and reliability.[9] To assess the foods displaced with the inclusion of eggs in the diets, we analyzed the 12 components of the HEI–2010 of our study participants.

Statistical analysis
Generalized linear models were used to assess difference between the egg inclusion versus egg exclusion diets. Paired Student's t-tests were used to assess difference from baseline to endpoints. Regression models were used to adjust for potential confounding factors (ie, age, gender, race, compliance, and treatment sequence). All analyses at end points were based on intention-to-treat principle. p Values of <0.05 were considered statistically significant. SAS software for Windows V.9.3 was used to carry out all statistical analyses. Data are presented as mean ± SD except otherwise stated.

Results
Demographic characteristics and baseline data
Our study participants were predominantly male (ie, 58.8%) and were mostly white (ie, 76.5%). The average age of the study participants was 64.5 years, and their average diet quality score was 52.9 out of a maximum possible score of 100. The average intakes of the different components of the subscales of the HEI are presented in table 1.

Efficacy data
When compared with egg exclusion, the inclusion of eggs in the diets of type 2 diabetes for 12 weeks

Table 1 Baseline characteristics

Variable	Mean ± SD
2010 Healthy Eating Index score	52.9±11.0
Total vegetables*	3.5±1.2
Greens and beans*	1.9±1.6
Total fruit†	2.6±1.9
Whole fruit‡	2.6±1.9
Whole grains	3.3±2.8
Dairy§	5.7±2.7
Total protein foods¶	4.3±0.8
Seafood and plant proteins¶,**	2.0±1.5
Fatty acids††	4.2±2.3
Sodium	3.3±2.4
Refined grains	6.1±2.7
Empty calories‡‡	13.8±3.9

*Includes any beans and peas not counted as total protein foods.
†Includes 100% fruit juice.
‡Includes all forms except juice.
§Includes all milk products, such as fluid milk, yogurt, and cheese, and fortified soy beverages.
¶Beans and peas are included here (and not with vegetables) when the total protein foods standard is otherwise not met.
**Includes seafood, nuts, seeds, soy products (other than beverages), as well as beans and peas counted as total protein foods.
†† Ratio of polyunsaturated and monounsaturated fatty acids to saturated fatty acids.
‡‡Calories from solid fats, alcohol, and added sugars; threshold for counting alcohol is >13 g/1000 kcal.

Table 2 Change in outcome measures from baseline

Variable	Eggs exclusion phase	Eggs inclusion phase	p Value
2010 Healthy Eating Index score	−3.5±12.7	−0.1±11.4	0.2572
Total vegetables	−0.1±1.5	−0.1±1.1	0.9605
Greens and beans	−0.4±2.0	−0.3±1.9	0.7050
Total fruit	0.2±1.0	0.3±1.5	0.8299
Whole fruit	0.4±1.2	0.1±1.7	0.3611
Whole grains	0.4±3.5	−0.6±3.1	0.2143
Dairy	−1.3±2.9*	−0.5±2.9	0.7767
Total Protein Foods	−0.1±1.0	0.3±0.7*	0.0789
Seafood and plant proteins	−0.1±1.8	0.0±1.5	0.7767
Fatty acids	−0.3±3.6	0.1±3.2	0.6103
Sodium	0.7±2.7	0.1±3.0	0.4340
Refined grains	0.7±2.2	−0.7±3.4	0.0530
Empty calories	1.0±5.7	−0.6±3.7	0.1786

Values are mean ± SD.
*Significant (p value<0.05) change from baseline.

non-significantly decreased the consumption of refined grains (−0.7±3.4 vs 0.7±2.2; p=0.0530) and non-significantly increased the consumption of total protein foods (ie, beans and peas are included here (and not with vegetables)) (0.3±0.7 vs −0.1±1.0; p=0.0789). No significant (p>0.05) changes were observed during the egg inclusion phase as compared with the egg exclusion phase in intake of total vegetables; greens and beans; total fruit (ie, 100% fruit juice); whole fruit (ie, all forms except juice); whole grains; seafood and plant proteins; fatty acids (ie, ratio of polyunsaturated and monounsaturated fatty acids to saturated fatty acids); sodium; empty calories (ie, calories from solid fats, alcohol, and added sugars); and overall diet quality.

The consumption of total protein foods significantly increased from baseline (0.3±0.7; p=0.0153) with the inclusion of eggs for 12 weeks. The consumption of dairy products (ie, all milk products, such as fluid milk, yogurt, and cheese, and fortified soy beverages) significantly decreased from baseline with the exclusion of eggs in the diets (−1.3±2.9; p=0.0188) (see table 2).

DISCUSSION

The inclusion of eggs in the diets of adults with type 2 diabetes significantly increased the consumption of total

protein foods from baseline. While the exclusion of eggs in the diets of type 2 diabetes significantly decreased the consumption of dairy from baseline. Compared with the exclusion of eggs, the inclusion of eggs non-significantly decreased the intake of refined grains. No meaningful improvements were observed in intake of total vegetables; greens and beans; total fruit; whole fruit; whole grains; seafood and plant proteins; fatty acids; sodium; or empty calories with the inclusion of eggs.

In a meta-analysis by Viguiliouk et al,[10] replacing animal proteins with plant proteins improved glycemic control in individuals with diabetes. In previous epidemiological studies,[11–13] consumption of vegetable proteins was associated with a reduction in type 2 diabetes, while the consumption of animal proteins was associated with an increased risk. In another epidemiological study, Pan et al[14] demonstrated an association between animal protein consumption and the risk of type 2 diabetes. A mediation analysis by Li et al[12] demonstrated that the effects of proteins on the risk of type 2 diabetes were mediated through the insulin sensitivity. Plant-based proteins such as beans, lentils, peas, and nuts have a low glycemic index, and they provide quality protein, healthy fatty acids, and fiber that help with weight loss and blood glucose control and that improve insulin sensitivity.

While we observed a meaningful reduction of refined grain consumption with the inclusion of eggs in the diets, we did not see a statistically significant reduction. The lack of statistical significance may be due to the small sample size, a placebo effect, and/or the Hawthorne effect. In a recent randomized trial by Kim et al,[15] short-term consumption of diets rich in red processed meat

and refined grains led to a decreased in insulin sensitivity compared with diets high in whole grains, nuts, dairy products, and legumes in insulin-resistant adults. In another randomized control trial, whole-grain cereal-based diets compared with refined cereal diets reduced postprandial insulin in individuals with metabolic syndrome.[16] Diets rich in red meat and refined grains have been shown to increase glucose and insulin response, which may increase pancreatic stress that could in turn increase the risk of type 2 diabetes.[17]

The inclusion of eggs in the diets of our study participants did not show any meaningful change in the consumption of dairy products, while the exclusion of eggs in the diets led to a significant reduction. The effects of dairy products on type 2 diabetes are controversial. In prospective epidemiological studies,[18 19] low-fat fermented dairy product consumption was associated with a lower risk of developing type 2 diabetes. In an epidemiological study by Chen et al,[20] higher consumption of yogurt was associated with lower risk of type 2 diabetes, while intake of other dairy foods or total dairy was not associated with the incidence of type 2 diabetes risk. A large European prospective study[21] showed no association between total dairy consumption and the risk of type 2 diabetes, but observed an inverse association with cheese consumption and combined fermented dairy. In another study,[22] the consumption of dairy foods was inversely associated with the prevalence of obesity. Wang et al[23] showed that higher total dairy and yogurt consumption were associated with body weight and waist circumference maintenance.

We did not see meaningful beneficial effects in consumption of total vegetables; greens and beans; total fruit; whole fruit; whole grains; seafood and plant proteins; fatty acids; sodium; and empty calories with the inclusion of eggs in the diets, possibly due to small sample size, placebo effect, and/or or the Hawthorne effect. Increased dietary consumption of total vegetables; greens and beans; total fruit; whole fruit; whole grains; seafood and plant proteins; and healthful fatty acids, and the reduced consumption of sodium and empty calories has been shown to improve cardiometabolic risk in type 2 diabetes.[24–40]

Limitations

This study has several limitations. First, the sample size of the study was small, limiting the ability to detect significant findings in some variables. However, the statistical power of the study was improved by using a crossover study design. Second, the study population was predominantly male and white, which limits the ability to extrapolate the study findings to a much broader population demographic. Third, due to the nature of the study intervention, the study participants were not blinded, which could have led to placebo or Hawthorne effects. Fourth, the dietary intakes of the study participants were self-reported. It is possible that the study participants would have underestimated or overestimated their food and beverage consumption. However, their dietary data were captured using a reliable, validated tool (ie, ASA-24) that provided specific directions to estimate their portion sizes and the percent of each portion size that they actually consumed, which minimized the likelihood of underestimation or overestimation of their dietary intake. In addition, the study dietitian provided guidance to the study participants on how to enter their dietary data. Fifth, the study participants were not supervised while consuming the foods and beverages during each study phase. Therefore, the veracity of these dietary data reported depends on the honesty of the study participants. However, this may be viewed also like strength of this study because it emulates a real-world scenario.

Conclusions

These data suggest that the inclusion of eggs in the diets of type 2 diabetics facilitated the intake of protein foods and reduced the intake of refined grains. In general, this study highlights the impact of single-food inclusions or exclusions on other dietary choices, and potentially, overall diet quality. The small sample studied here limited the statistical power to identify relevant associations and argues for larger studies to examine the impact of food-specific recommendations on dietary pattern, particularly in at-risk groups such as those with type 2 diabetes.

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