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Do all patients with type 2 diabetes need breakfast?

*Tina Parkner, MD, PhD^{1,2}, Jannik Kruse Nielsen, MD, PhD¹, Thomas Damgaard Sandahl, MD^{1,3},
Bo Martin Bibby, PhD⁴, Birgit Schelde Jensen, RD¹ and Jens Sandahl Christiansen, DMSc¹*

¹ Department of Endocrinology and Diabetes, Aarhus University Hospital, Aarhus; ² Department of Clinical Biochemistry, Aarhus University Hospital, Aarhus; ³ Department of Hepatology and Gastroenterology, Aarhus University Hospital, Aarhus; ⁴ Department of Biostatistics, University of Aarhus, Aarhus; All in Denmark

Running title:

Type 2 diabetes and breakfast

Corresponding author:

Tina Parkner
Department of Clinical Biochemistry
Aarhus University Hospital
Norrebrogade 44
8000 Aarhus C
Denmark
Tel: + 45 4159 1434
Fax: + 45 8949 3047
E-mail: tparkner@dadlnet.dk

Abstract:

Objectives: To evaluate if an improved daily glycaemic profile could be achieved in patients with type 2 diabetes by withholding breakfast, but maintaining the same total daily intake of calorie and the same composition of carbohydrates, fat, and protein.

Methods: Thirteen type 2 diabetic patients participated in this randomised crossover study.

Following an initial fasting night the study consisted of 4 consecutive days. Patients were randomised to diets including breakfast day 1 and 3, and excluding breakfast day 2 and 4, or vice versa.

Results: The mean plasma glucose level was 0.24 mmol/l higher after the breakfast diet compared to the non-breakfast diet, but reflected only a tendency ($P=0.066$). The standard deviation based on plasma glucose was 32% higher after the breakfast diet compared to the non-breakfast diet ($P<0.0001$).

Conclusions: Not all patients with type 2 diabetes may need breakfast. Moreover, a non-breakfast diet reduces glycemic variability.

Keywords: Type 2 Diabetes Mellitus; Diabetic Diet; Diet.

Main text:

Hyperglycemia after breakfast occurs in many patients with type 2 diabetes even when treated with oral antidiabetics or/and insulin (American Diabetes Association 2001). Considerable attention has been focused on the importance of postprandial hyperglycemia as a risk factor for cardiovascular disease (Gerich 2003) and as a rate-limiting factor for achieving optimal glycaemic control in these patients (Woerle et al. 2007). Moreover, achieving minimal intra-individual within-day and day-to-day glucose variability is also important for tailored sufficient treatment and seems to reduce diabetic complications (Monnier et al. 2008). However, consensus data on favourable frequency of meals including need of breakfast or not for patients with type 2 diabetes are unavailable.

Thirteen patients with type 2 diabetes were recruited (Table 1). Inclusion criteria were: Type 2 diabetic patients treated with diet and/or one or two antidiabetic drugs. Exclusion criteria were: Not insulin naive patients and concomitant disorders or medications judged to influence the study.

The trial was a randomised crossover study. The patients were hospitalised the evening before the first of 4 consecutive study days in the hospital setting. They received a standardized evening meal and they fasted from 10 pm. The next morning the study began at 8 am. Each patient received a randomised diet schedule that is begun on a day with (7 patients) or without breakfast (6 patients). Every other day the breakfast regime shifted. At the 2 separated breakfast days the daily energy distribution were as following: At breakfast (8 am) 25%, at lunch (12 noon) 25%, at first snack (3 pm) 10%, at dinner (6 pm) 30% and at a late snack (8 pm) 10% of the daily total energy intake was consumed, whereas on the 2 days without breakfast the distribution were 0%, 35%, 15%, 35% and 15%, respectively. The standardised meals were adjusted to ensure the *same total daily energy intake* on all study days.

Prior to the study three different energy levels for daily diet regimes were defined: 8372 kJ/day, 10465 kJ/day or 12558 kJ/day. Each patient was assigned to one of these energy levels for the 4 study days based on each patient's basic metabolic rate multiplied by an activity factor of 1.3. Each meal contained 55% of the energy as carbohydrate, 30% as fat and 15% as protein. Moreover, each participant chose between walks for half an hour 2 or 3 times per day. For each patient exercise was to be exactly the same and to be carried out on the same time on all days.

Plasma glucose profiles were measured by bedside standard plasma calibrated GlucoMeter (Accu-Chek[®]) each hour from 8:00 am–8:00 pm and one time during the night at 3 am.

The mean plasma glucose level based on measurements over the whole day (8 am-3 am) was 0.24 mmol/l higher after the breakfast diet compared to the fasting diet, though only reflecting a tendency (95%-CI:-0.02-0.50 mmol/l; P=0.066) (Figure 1). When based only on the measurements obtained before lunch (8 am-12 noon), the mean plasma glucose level was clearly significantly higher after the breakfast diet compared to the fasting diet (1.44 mmol/l, 95%-CI:1.10-1.79 mmol/l; P<0.0001). After lunch (1 pm-3 am) the mean plasma glucose level was significantly higher after the fasting diet compared to after the breakfast diet (0.43 mmol/l, 95%-CI:0.09-0.77 mmol/l; P=0.0153).

The standard deviation based on plasma glucose measurements for the whole day (8 am-3 am) was 32 % higher on the diet including breakfast compared to the fasting diet (95%-CI:18-49%; P<0.0001). Before lunch (8 am-12 noon) the difference between the breakfast diet and the fasting diet regarding the standard deviation was even more pronounced (260% higher after breakfast, 95%-CI:172-378%; P<0.0001). When based solely on plasma glucose measurements after lunch (1 pm-3 am) there was no significant difference between the two diets (2% smaller after the breakfast diet, 95%-CI:-17-16%; P=0.84).

The American Diabetes Association recommends peak post-prandial plasma glucose (PPPG) to be <10 mmol/l. The International Diabetes Federation (IDF) recommends near normal 2-hour PPPG values of ≤ 7.8 mmol/l (International Diabetes Federation 2007). Our data show mean post-prandial breakfast glucose levels exceeding the IDF recommendation on breakfast days but not on the fasting diet. An interesting observation was that none of the patients felt hungry during the mornings with fasting and no hypoglycaemic events were recorded during these mornings.

Post-prandial hyperglycemia, especially in the lower categories of HbA_{1c}, has been suggested as an independent risk factor for macrovascular disease, the major cause of death in type 2 diabetes (Cavalot et al. 2006). Furthermore, in most of these patients, the post-meal excursions are longer than normal and follow an ordinal decreasing scale that can be described as post-breakfast > post-dinner or post-lunch excursions (Monnier et al. 2007). This is in accordance with our study at breakfast diet days. However, the mean plasma glucose level based on measurements over the whole day was higher after the breakfast diet compared to the fasting diet, but reflected only a tendency. Moreover, weaknesses of our small pilot study include a lack of data from 3 am-8 am and not using a continuous glucose monitoring system for measuring the complete plasma glucose profiles (Monnier, Colette, and Owens 2008). **It should also be acknowledged that some data have suggested that less frequent meals, and especially lack of breakfast, are associated with weight gain (Berg et al. 2009).**

The glycemic variability, based on plasma glucose measurements for the whole day, was significantly higher after the breakfast diet compared to the non-breakfast diet. Before lunch the difference was even more pronounced, which was expected, as patients with type 2 diabetes in particular **have** various **degrees** of insulin resistant in the morning hours. Thus, the glycemic

disorders in type 2 diabetes are not limited to hyperglycemia but can be extended to the glycemic variability that includes both upward and downward glucose changes (Monnier and Colette 2008). In type 2 diabetes blood glucose fluctuations have been found to be relevant to the progression of arterosclerosis and to correlation strongly with macrovascular complications (DECODE Study Group 2001). Moreover, it has been demonstrated that intra-day blood glucose excursions may have a pronounced effect on carotid intima-media thickness progression (Chen et al. 2010). This could suggest that glucose variations may be a major contributor to the development of vascular injury. In conclusion, not all patients with type 2 diabetes may need breakfast. Moreover, a non-breakfast diet seems to reduce glycemic variability.

Conflict of interest:

None of the authors have any competing financial interests in relation to the study described.

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Figure legends

Figure 1: Mean plasma glucose (mmol/l) with 95%-confidens intervals for the thirteen patients with type 2 diabetes during the 4 consecutive study days with or without breakfast, respectively.

Age (years)	58 (24-68)
BMI (kg/m ²)	29.8 ± 4.4
Duration of diabetes (years)	5 (1-14)
HbA1c (%)	7.1 ± 1.1
Total cholesterol (mmol/l)	4.2 ± 1.2
Systolic BP (mmHg)	136 ± 20
Diastolic BP (mmHg)	80 ± 5
Daily number and dose of oral glucose-lowering agent (mg)	
2 patients on diet only	
7 patients on one agent:	
• Metformin	1500 (1000-2000)
4 patients on two agents:	
• Metformin + glimepiride	3000 (3000-3000) + 2.5 (2-3)
• Metformin + glibenclamide	1500 (1000-2000) + 7.9 (1.75-14)

Table 1.

Mean ± SD or median (range) characteristics for the thirteen patients with type 2 diabetes at baseline.

Figure 1.

