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Title	The Effect of Apple Fibre on Diabetic Control and Plasma Lipids
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Publication date	1982
Publication information	Mayne, P.D., A.R. McGill, T. R. (Thomas Ronan) Gormley, and et al. "The Effect of Apple Fibre on Diabetic Control and Plasma Lipids" 151, no. 2 (1982).
Publisher	Springer
Item record/more information	http://hdl.handle.net/10197/6894

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IRISH JOURNAL OF MEDICAL SCIENCE

Official Organ of the Royal Academy of Medicine in Ireland.

Established 1832

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Reprinted from Vol. 151, No. 2, February, 1982, pp. 36-41

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Summary

THE purpose of the study was to investigate the effect of apple fibre on diabetic control and on plasma lipid levels in non insulin dependent maturity onset diabetes mellitus. Twelve patients (8 females and 4 males) ingested 15g of apple fibre per day over a period of 7 weeks. There was a significant improvement in diabetic control, as reflected by a fall in mean fasting plasma glucose ($P < 0.05$) and in percentage glycosylated haemoglobin ($P < 0.005$). There was a 5% decrease in plasma cholesterol and 4% increase in HDL-cholesterol with no change in plasma triglyceride. These results suggest that apple fibre may be a useful adjuvant in the management of non insulin dependent maturity onset diabetic patients.

Introduction

In recent years there have been a number of reports in the medical literature which demonstrate the effect of dietary fibre on glucose absorption and diabetic control. Trowell (1975) has presented the hypothesis that in a susceptible individual fibre depleted foods may be associated with the development of diabetes mellitus. In published studies, the source, quantity and duration of fibre ingestion varied considerably as

did the responses observed. Wheat bran, guar and pectin (Jenkins *et al*, 1978, 1979) flatten the hyperglycaemic curve and insulin response following a glucose load and may improve diabetic control. Guar (Jenkins *et al*, 1975) and pectin (Durrington *et al*, 1976) decrease serum cholesterol in diabetic patients and in healthy volunteers. Guar and pectin, however, are unpalatable and may cause nausea, abdominal cramps and flatus.

Diabetic control may be monitored by plasma or urine glucose estimations. More recently the percentage of glycosylated haemoglobin $HbA_{1(a+b+c)}$ has been considered a useful indicator of diabetic control over the preceding 6 to 8 weeks (Gonen *et al*, 1977; Gabbay *et al*, 1977). Maturity onset diabetic patients have a low serum concentration of high density lipoprotein (HDL)-cholesterol (Kennedy, 1978), this being associated with an increased risk of ischaemic heart disease (Miller *et al*, 1977; Gordon *et al*, 1977). Lopes-Virella *et al* (1977) have claimed that well controlled male diabetic patients have significantly higher serum HDL-cholesterol concentrations than have patients with elevated serum glucose and/or lipid levels.

Patients and Methods

Twelve patients (8 women and 4 men) completed the study, having given informed consent. They were all non

* Based on P. D. Mayne's Registrars Prize, Royal Academy of Medicine in Ireland, 1979.

insulin dependent diabetic patients, being treated by diet alone. There were no other concurrent illnesses and no patient was taking any medication. Three other patients entered the trial but withdrew, 2 due to transport difficulties and one due to business commitments. All patients were caucasian with a mean age of 63.2 ± 2.60 years (range 48-76).

Each patient, following an overnight fast, attended the diabetic clinic for 2 consecutive weeks. Venous blood was drawn from an antecubital vein with minimal stasis and analysed for HbA_{1c} , plasma glucose, cholesterol, HDL-cholesterol and triglyceride. Each subject was then given a weighed quantity of apple fibre and asked to add 5g 3 times a day to their usual diet in the form of a slurry. Compliance was assessed each week by weighing the amount of fibre remaining, when the patient returned for further venous sampling. The study lasted for 7 weeks and then each patient was asked to attend on a further 2 occasions, the first and eighth week following the study period. Before entering the trial and at intervals throughout, the patients were assessed by a dietitian to ascertain whether there had been any alteration in their diet or caloric intake.

Plasma for lipid estimations was separated within 3 hours of collection and stored at -20°C until assayed. All individual patient samples were analysed in the same assay to avoid between-batch variation. Standard enzymatic laboratory methods were used for the analysis of total plasma cholesterol (Roschlau *et al*, 1975) and triglyceride (Stein and Horn, 1972). Plasma HDL-cholesterol was measured by a modification of the technique of Burnstein and Samaille (1960). Blood for glucose and HbA_{1c} estimation was collected in fluoride oxalate. Plasma glucose was assayed using an established autoanalyser method, and HbA_{1c} was assayed by the method of Welch and Boucher (1978) at room temperature ($20.3 \pm 0.25^\circ\text{C}$). Lysates for

quality control were prepared from volunteers and stored at -20°C . Within batch coefficient of variation was 4.3% and between batch coefficient of variation 6.8%. For non diabetic patients the mean value of HbA_{1c} was $7.9 \pm 0.32\%$ (range 5.0-10.7%), while for established diabetic patients this was $12.9 \pm 0.47\%$.

The apple fibre was prepared by dicing mature Golden Delicious apples (1 cm approx. cores and skin included). The dices were freeze-dried and then the material was powdered in a hammer mill and extracted with aqueous ethanol (20% water) at reflux for 1 hour using a batch size of 2.5 kg of freeze-dried apples and 21 litres of aqueous ethanol. The residue was collected in large Buchner funnels (vacuum applied), washed with 11 litres of boiling aqueous ethanol and dried at less than 30°C . The residue was termed "Apple Fibre", the percentage composition of which is shown in Table I. One hundred kg of fresh apples gave 11.12 kg of freeze-dried apple which gave 2.41 kg of apple fibre.

TABLE I
Percentage composition of apple fibre by weight.

Constituent	Percentage
Pectin	17.2
Protein	8.8
Moisture	7.7
Ash	2.2
Fat	2.0
Cellulose	62.1 * calculated by difference
Hemicellulose	
Lignin	
Total	100

Results are expressed as mean $\pm$ standard error of the mean ($\bar{x} \pm \text{SEM}$). Statistical analyses were performed using the student's paired 't' test and the Wilcoxon matched-pairs signed-ranks test (Siegel, 1956) for non parametric data.

Results

The apple fibre was well tolerated by all patients, being readily acceptable and palatable. There were no side effects noted, with no noticeable increase in stool volume or frequency. There was no significant alteration in caloric intake or mean body weight throughout the study. The initial mean weight was 70.59 ± 2.83 kg and 70.73 ± 2.90 kg during the seventh week of the trial.

The initial fasting plasma glucose level was 9.6 ± 0.89 mmol/l and the mean $HbA_{1(a+b+c)}$ value $12.0 \pm 0.52\%$. The correlation coefficient between initial plasma glucose and $HbA_{1(a+b+c)}$ was 0.73 ($P < 0.01$).

During the 7 week study period on apple fibre there was an 8.0% decrease in mean fasting plasma glucose concentration ($P < 0.05$) with no significant difference between the pre and post study fasting levels. There was a significant decrease in $HbA_{1(a+b+c)}$ by the seventh week of the study ($P < 0.01$) and on the first week following the study ($P < 0.0005$). By the eighth week there had been an increase of $HbA_{1(a+b+c)}$ ($P < 0.01$) although it had not returned the pre-study level ($P < 0.002$). By the seventh week on apple fibre, there had been a 5% decrease in plasma cholesterol and a 4% increase in HDL-cholesterol (neither of which reached statistical significance), there was no change in plasma triglyceride concentration (Table II). There was no correlation between HDL-cholesterol and percentage $HbA_{1(a+b+c)}$.

It was discovered in retrospect that one patient was not fasting on all occasions when sampled. This does not affect the $HbA_{1(a+b+c)}$, plasma cholesterol or HDL-cholesterol (Kennedy *et al*, 1978). We re-analysed the fasting glucose and triglyceride results excluding his data. There was a more significant decrease in mean plasma glucose ($P < 0.005$) and a 7% decrease in plasma triglyceride. The serial changes in glucose and $HbA_{1(a+b+c)}$ are illustrated in Fig. 1.

Fig. 1 — The effect of apple fibre on plasma glucose and HbA_{1c} . (Mean $\pm$ SEM)

TABLE II

	Pre	Study 3rd week	7th week	Post 1st week	8th week
	Mean SEM	Mean SEM	Mean SEM	Mean SEM	Mean SEM
Cholesterol mmol/l	5.99 ± 0.36	5.92 ± 0.27	5.59 ± 0.26	5.72 ± 0.27	5.91 ± 0.25
HDL-Cholesterol mmol/l	1.51 ± 0.076	1.56 ± 0.081	1.57 ± 0.081	1.57 ± 0.085	1.52 ± 0.057
Triglyceride mmol/l	2.01 ± 0.20	1.85 ± 0.17	2.04 ± 0.24	1.87 ± 0.17	1.95 ± 0.24

Discussion

We have demonstrated that on adding 15 g of apple fibre per day (containing 2.6 g of pectin) to the normal diet of non-insulin dependent maturity onset diabetic patients, there was a significant improvement in diabetic control, as reflected by a fall in mean fasting plasma glucose concentration and percentage $HbA_{1(n+b+c)}$. By the eighth week following the study the mean plasma glucose had returned to the pre-study level, there being a significant increase in $HbA_{1(n+b+c)}$ although it was still lower than the pre-study level. This, probably, reflects a worsening in diabetic control following withdrawal of the apple fibre.

The effect of dietary fibre on diabetic control has long been recognised. Kiehm *et al* (1976) were able to reduce insulin treatment in a group of mild diabetic patients when fed a high fibre, high carbohydrate diet for 2 weeks. However, in 3 patients on larger doses of insulin, no effect was noted. In 8 insulin dependent diabetics Jenkins *et al* (1980) have shown that the addition of guar crispbread (14.26 g per day for at least 6 months) to the diet led to improved diabetic control, with a reduction in 24 hour urine glucose output and lowered insulin requirements. There was also a statistically significant reduction in total serum cholesterol.

Pectin has been shown to have a hypocholesterolaemic effect. Durrington *et al* (1976) observed an 8% decrease in cholesterol levels when 12 healthy volunteers took 12 g of pectin per day for 3 weeks. Gormley and his colleagues (1977) also found an 8% decrease in 38 healthy subjects who were on a high apple intake over a 4 month period. They postulated that the hypocholesterolaemic effect might be due to the pectin content of the apples. We observed a 5% fall in total plasma cholesterol. It is possible that by increasing its palatability, a greater hypocholesterolaemic effect might have been achieved.

Serum HDL-cholesterol is decreased (Kennedy *et al*, 1978) and triglyceride (Simpson *et al*, 1979) increased in maturity onset diabetics. A significant correlation between diabetic control and HDL-cholesterol had been reported (Lopes-Virella *et al*, 1977; Calvert *et al*, 1978) but has not been confirmed by others (Kennedy *et al*, 1978; Yudkin *et al*, 1979; Stanton, 1978). Calvert *et al* (1978) found an inverse correlation between HDL-cholesterol and $HbA_{1(n+b+c)}$ in 122 patients. In a subgroup of 8 insulin dependent patients a fall in percentage $HbA_{1(n+b+c)}$ was associated with an increase in HDL-cholesterol. Michael *et al* (1979) demonstrated that in a group of 6 maturity onset diabetics improved diabetic control resulted in an increase in HDL-cholesterol and decrease in triglyceride. Alterations in plasma lipids were not observed in other patients receiving similar treatment; they consider that this may reflect heterogeneous diabetic populations. Nikkila (1978) has suggested that both in normal subjects and in diabetic patients the levels of HDL-cholesterol are influenced by the metabolism of triglyceride rich lipoproteins. Therefore, improvement in diabetic control might be expected to alter HDL-cholesterol concentrations only in those patients who were hypertriglyceridaemic.

Indeed, the low HDL-cholesterol concentrations in diabetic patients, described by Lopes-Virella *et al* (1977) were usually associated with hypertriglyceridaemia. In our study, there was a 4% increase in mean HDL-cholesterol concentration, a sustained increase occurring in 9 of the 12 patients. Seven of these 9 patients (78%) were hypertriglyceridaemic on entry into the trial, but although there was no concomitant fall in plasma triglyceride concentrations. However, unlike the patients of Lopes-Virella (1977), our patients were only mildly hypertriglyceridaemic.

We consider that the trends observed in this study may be important. It is also

reassuring that the changes in plasma lipids, although small, are in a direction which might well be beneficial (Miller *et al*, 1977; Gordon *et al*, 1977), particularly in view of the recognised increase in incidence of cardiovascular disease in maturity onset diabetes (Keen *et al*, 1965). It was not possible to ascertain whether the responses observed in plasma lipids were due to improved diabetic control or to a direct effect of the apple fibre.

Throughout the study, there was no increase in bodyweight nor significant alteration in caloric intake which could account for improved diabetic control. It is possible that the benefits might diminish with time, the biochemical changes being to some extent a reflection of intensive medical surveillance. However, in a similar 'free range' study over 6 months to 2 years, the Oxford group (Jenkins *et al*, 1980) using guar crispbread demonstrated that the long term improvements in diabetic control were similar to those in their earlier short term studies (Jenkins *et al*, 1978-1979). Due to limited supplies of fibre there was no patient control group. However, we made every effort to ensure that each patient acted as his or her own control. It was stressed that the only alteration in diet which we required was the addition of the apple fibre to their usual food. We were satisfied with patient compliance regarding the ingestion of apple fibre.

From these biochemistry results, we believe that apple fibre may be a beneficial adjuvant in the management of maturity onset diabetic patients, having an effect on diabetic control and on plasma lipids. Apple fibre is palatable and acceptable to patients and is stable, easily stored and relatively inexpensive if extracted in bulk.

We thank Miss O'Shaughnessy, dietitian, Federated Dublin Voluntary Hospitals, Comhlucht Siuicre Eireann Teo. for freeze drying the apples and Ceimici Teo for the alcohol used in the preparation of the dietary fibre.

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