

## **Gestational diabetes; can a low glycemic index diet reduce the need for insulin? A randomised trial**

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*Background* A low glycemic index (GI) diet is effective as treatment for people with diabetes and has been shown to improve pregnancy outcomes when used from the first trimester. A low GI diet is commonly advised as treatment for women with gestational diabetes mellitus (GDM). However the efficacy and pregnancy outcomes of this advice have not been systematically examined.

*Objective* To determine if prescribing a low glycemic index (GI) diet for women diagnosed with GDM could reduce the number of women requiring insulin without compromise of pregnancy outcomes.

*Design* All women with GDM seen over a 12-month period were considered for inclusion in the study. Women (n = 63) were randomised to receive either a low GI diet or a conventional high fiber (and higher GI) diet

*Results* Of the 31 women randomised to a low GI diet, 9 (29%) required insulin. Of the women randomised to a higher GI diet, a significantly higher proportion, 19/32 (59%), met the criteria to commence on insulin ( $p = 0.023$ ). However 9 of these 19 women were able to avoid insulin use by changing to a low GI diet. Key obstetric and fetal outcomes were not significantly different.

*Conclusions* Using a low GI diet for women diagnosed with GDM effectively halved the number needing to use insulin with no compromise of obstetric or fetal outcomes.

**G**estational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy (1). GDM is associated with an increase in adverse pregnancy outcomes and the advantages of treatment on these outcomes have been identified (2). All women with GDM should have medical nutrition therapy (MNT) with the objective of achieving and maintaining blood glucose levels as close to the normal range as possible (3). MNT needs to be individualised and based on carbohydrate distribution and ideally the results of self-monitoring of blood glucose (SMBG). For the purposes of SMBG, a combination of the fasting and postprandial glucose levels is desirable.

When MNT alone is unable to keep the results of SMBG within predetermined target ranges, alternative therapies are required. While there is some evidence that both glyburide (4) and metformin (5) can be used, the overwhelming experience has been with insulin. However the potential use of insulin can be a source of both anxiety and of resistance to treatment change.

In normal subjects, mixed meals based on low glycemic index (GI) foods lead to a reduction in postprandial glycemia (6). We have previously demonstrated in normal pregnant women that a diet based on low GI foods were sustainable and resulted in more favourable fetal outcomes (7).

The aim of this study was to examine whether a low GI diet used as MNT for women with GDM could result in a reduced need for insulin use during pregnancy with no compromise of obstetric and fetal outcomes.

## **METHODS**

The study was conducted in the city of Wollongong, NSW Australia; a coastal city with a population of around 280,000 people situated about 50 miles south of Sydney. The

Australasian Diabetes in Pregnancy Society (ADIPS) recommends that all pregnant women should be tested for GDM (8). Unless indicated earlier, women have a 75g GTT at the beginning of the third trimester with glucose samples taken fasting and at 2-hours. GDM is diagnosed if the fasting glucose is  $\geq 5.5$  mmol/L ( $\sim 100$ mg/dl) and/or the 2-hour glucose is  $\geq 8.0$  mmol/L ( $\sim 145$ mg/dl) (10). Virtually all women diagnosed with GDM are seen at the Diabetes Centre by a diabetes nurse educator and a specialist dietitian. All women seen over a 12-month period, Oct 2007 to Sept 2008, were considered. There are approximately 3,300 deliveries each year in the area including both the public and private hospitals. The prevalence of GDM is around 7% and there is more than 90% compliance with universal testing (9).

Inclusion criteria; age 18 – 40 years (inclusive), singleton pregnancy, no previous GDM, non-smoker, diagnosed with GDM and seen for the first dietary visit between 28 and 32 weeks of gestation and able to follow the protocol requirements. Exclusion criteria included any condition or medication that could affect the glucose levels and any woman who would be unwilling to follow the prescribed diet.

After diagnosis of GDM and assessment by a physician (RGM), all women attended the Diabetes Center. If they were potentially interested in the study they were asked to complete a 3-day food record prior to the first visit with the dietitian. This record was used for the initial dietary assessment. This visit was completed between 28 and 32 weeks of gestation. Visits 2 and 3 were conducted about 1-2 and 3-4 weeks respectively after the initial visit with a 7-day food record that was used to calculate GI. The final visit was at 35 – 37 weeks of gestation with a 3-day food record that was used to compare with the food record at visit 1. Thus all women were seen at least four times for

dietary assessment and, if insulin requiring, as many times as necessary for insulin adjustment.

Weight was measured to the nearest 0.1 kg on floor scales (HD-316, Wedderburn Scales, Tanita Corporation, Toykyo, Japan) with subjects dressed in light clothes and without shoes. Height was measured to the nearest 0.1 cm against a wall using a nonstretchable fiberglass measuring tape (Gulick II, Country Technology, Inc Gays Mills, Wisconsin USA).

Women who met the inclusion criteria and had no exclusions were randomized to receive one of two different diets using permuted blocks of unequal size with the list generated using STATA (V 7.0).

Both diets were compatible with the recommended nutritional intake in pregnancy (10). The carbohydrate (CHO) intake was designed to achieve a minimum of 175 g/day with only the recommended choice of CHO foods varying. The dietary advice was individualised with specific mention of the energy and nutrient balance to achieve normal weight gain during the third trimester. The low GI diet (LGI) was based on previously verified low GI food (11), including pasta, grain breads and unprocessed breakfast cereals with a high fiber content. Women were specifically asked to avoid using white bread, processed commercial breakfast cereals, potatoes and some rice varieties. The conventional, higher GI diet (HGI) comprised advice to follow a diet with a high fiber and low sugar content with no specific mention of the GI. Potatoes, whole wheat bread and specific high fiber, moderate-to-high GI breakfast cereals were recommended. During clinic visits, the dietitian referred to the diets as the “low GI diet” or the “high fiber/low sugar” diet. Participants were provided with a booklet outlining the CHO choices as well as the CHO food amounts constituting one serving (based on 15 g portions). To assist with achieving stable blood glucose levels

throughout the day participants were advised to consume 3 small meals and 2-3 snacks with a specified number of servings of CHO. Study dietitians were not blinded to dietary assignment but were aware of the need for impartiality and equivalent treatment. The physician caring for the patients was not informed of the diet allocation.

Women were provided with a home glucose meter (Roche Accu-Check® Performa) and asked to test fasting and 1-hour after the start of each of their three major meals at least every second day. The use of insulin, unless there were exceptional circumstances, was advised if more than once a week the fasting glucose was  $\geq 5.5$  mmol/L and/or the 1-hour post prandial glucose was  $\geq 8.0$  mmol/L. Women on the low GI diet who exceeded these values were commenced on insulin immediately. Women on the higher GI diet who exceeded these values were changed to a low GI diet and their responses reviewed over a week. When indicated, insulin treatment was initiated with twice daily pre-mixed insulin (NovoMix 30®, NovoNordisk Pharmaceuticals) using a disposable pen device. The dose was adjusted regularly to achieve glycemic goals.

Food intake data for the baseline, V2, V3 and final visits for each participant were entered into a customised database incorporating the Australian food composition tables and published GI values using the glucose = 100 scale (FoodWorks™ Professional, Version 4 2005, Xyris Software, Highgate Hill, Qld, Australia). Where necessary, additional GI data were obtained from an online database ([www.glycemicindex.com](http://www.glycemicindex.com)). Overall dietary GI was calculated as the sum of the weighted GI of all carbohydrate foods in the diet, with the weighting proportional to the contribution of each food to the total carbohydrate intake. Because the target diets aimed for a similar carbohydrate content, glycemic load (the product of the GI and the amount of

carbohydrate) was influenced only by differences in GI.

Pregnancy care was the responsibility of the obstetric health care providers and was conducted in accord with standard practice. Because both diets were within the nutritional guidelines for pregnancy, the obstetric health care providers were not specifically informed of the diet allocation. Obstetric outcomes, including birth weight, fetal length and head circumference, Apgar score and method of delivery, were obtained from the medical record. For comparison between the two groups, the fetal centile was calculated from [www.gestation.net](http://www.gestation.net) using Australian data. By this means the birth weight was adjusted for gender, gestational week of delivery, maternal age, parity, height and pre-pregnancy weight by recall. The ponderal index (PI) of the baby was calculated using the formula weight (g) divided by the length<sup>3</sup> (cm) and multiplied by 100. The body mass index (BMI) of the mother was calculated by dividing the weight at enrolment (kg) by the height (m)<sup>2</sup>. The Illawarra Area Health Service and University of Wollongong Human Research Committee approved the research and participants gave written informed consent.

**Statistical analysis** Independent samples t-tests were used to compare the dietary components and the GI, GL and CHO values of the low GI and the high GI groups at the various appointment times. Pearson chi-squared tests of independence were used to compare proportions identified as needing insulin and actually starting on insulin in the low GI and high GI groups. SPSS version 14 (SPSS Inc, Chicago, Ill) was used for all statistical analyses. Unless otherwise stated results have been expressed as mean  $\pm$  SEM. Results were considered significant if  $p < 0.05$ .

## **RESULTS**

This study recruited for a 12-month period starting October 2007. Two hundred

and twelve women with GDM were seen over this period of which 63 met the criteria and agreed to participate in the study. Thirty-one were randomised to receive the low GI diet and 32 were randomised to receive the high fiber/low sugar diet – henceforth referred to as the high GI diet. All women except one were Caucasian. There were no significant differences in the baseline characteristics of the two groups as outlined in table 1.

A flow chart of the number of women in each diet group and their insulin requirements are shown in figure 1. In summary, the number of women in the low GI group who met the criteria to start on insulin (9 of 31, or 29%) was significantly lower than 19/32 women (59%) in the high GI diet ( $p = 0.023$ ). Of the 19 women in the high GI group who met the criteria to start on insulin who were then switched to the low GI diet, 9 no longer met the criteria to start insulin. Thus, after dietary changes, only 10/32 (31%) of the women in the high GI group required insulin and that was not significantly different to the 9/31 (29%) in the original low GI group. Insulin was initiated at  $32.1 \pm 0.4$  weeks for women in the low GI group and at  $32.3 \pm 0.5$  weeks for women in the high GI group ( $p = 0.83$ ). The total daily dose of insulin at term was  $24 \pm 2.2$  units.

The reported dietary intake assessed by a 3-day food record at baseline and at the final visit of the study is shown in table 2. There were no significant differences between the two groups at baseline with respect to energy and most nutrients except for a higher percentage of energy from protein in the women randomised to the high GI group ( $p < 0.009$ ). Between baseline and the final visit there was a significant reduction in total energy consumed in both groups due mainly to a reduction in the carbohydrate intake. There were no significant differences in the extent of this reduction between the two groups. The amount of protein consumed as a percentage of energy intake increased

significantly for both groups over the course of the study. The percentage of energy intake for monounsaturated fats, polyunsaturated fats and saturated fats was not significantly different between the groups and did not change during the study (data not shown).

The GI for all visits is shown in table 3. The GI at baseline was similar in both groups. The women randomised to the low GI diet achieved and maintained a significantly lower GI at all stages. The women randomised to the high GI diet that did not meet the criteria to start on insulin, and hence had no diet changes, had no significant change in GI during the course of the study. The women randomised to the high GI diet, who met the criteria to start on insulin, and were changed to a low GI diet (usually at or shortly after visit 2), achieved a significant reduction in GI by visit 3 and had a GI value similar to the original low GI group by the final visit.

There were no significant differences between the women in either group with respect to weight gain from baseline to delivery, induction of labour, method of delivery or the gestational age of delivery (data not shown). For women in the low GI group the birth centile ( $46.3 \pm 5.0$ ) and ponderal index ( $2.7 \pm 0.05$ ) were not significantly different to the birth centile ( $54.3 \pm 4.8$ ,  $p = 0.25$ ) and ponderal index ( $2.6 \pm 0.04$ ,  $p = 0.12$ ) for women in the high GI diet group. Three women in both groups had a LGA baby ( $\geq 90^{\text{th}}$  centile) and 2 women in the low GI group had a SGA baby ( $\leq 10^{\text{th}}$  centile). There were overall no significant differences in obstetric and fetal outcomes between the two groups.

The obstetric and fetal outcomes were further analysed with respect to comparing women who were and were not receiving insulin for (a) women on a low GI diet, (b) for women on a high GI diet and for (c) the two groups combined. There were no significant differences with respect to induction of

labour, method of delivery, fetal centile and ponderal index (data not shown).

## **DISCUSSION**

Two recent reports have shown the advantages of a low GI diet for the management of people with type 2 diabetes (12, 13). While evidence about the usefulness of a low GI diet in pregnancy is limited (14), we have previously shown that consumption of a low GI diet from the beginning of the second trimester resulted in better fetal outcomes (7). It has been usual practice in our clinic to encourage low GI choices when offering MNT to women diagnosed with GDM. However this recommendation was based on clinical experience and had not been formally examined. We therefore decided to extend the observations about the potential benefits of a low GI diet in pregnancy to women diagnosed with GDM.

It was impossible to blind women to the GI concept as it is widely known and discussed in the lay press. The inclusion criteria excluded any woman who was unwilling to follow the prescribed diet. The standard literature about GDM that was provided to all women was rewritten to remove reference to the GI of food. During recruitment and consenting, it was carefully explained to all women that the best diet for the treatment of GDM was not known and that this was the purpose of the study.

Women randomised to receive a low GI diet were able to lower the GI of their diet rapidly and maintain this for the duration of pregnancy. Women who were on a higher GI diet and, because they met the criteria to commence on insulin, were advised to change to a low GI diet also achieved this rapidly and were able to maintain this for the duration of the pregnancy. The final GI in both groups on a low GI diet was not significantly different. The fiber intake, which sometimes has been a confounding variable in determining the potential advantages of low GI diet, was

similar in both groups. Both groups of women self restricted their energy intake (and weight gain) by reducing the amount of carbohydrate consumed.

Women randomised to initially receive a low GI diet had a significantly lower rate of insulin use. All women on the higher GI diet who met the criteria to commence on insulin were changed to a low GI diet and about half no longer met the criteria and thus were able to avoid using insulin.

Insulin use for the women with higher glycemic levels resulted in a fetal centile and ponderal index that were not significantly different to the diet treated groups. In contrast to our previous study in normal women, the low GI diet for women with GDM did not result in a significantly lower fetal centile or ponderal index. It is very probable that this was related to the shorter duration of the diet for women with GDM compared with women started during the first trimester. However, demonstration of a difference was not the primary aim of the study and it was not powered for this purpose. While a trend was apparent, it is possible that a longer duration of a low GI diet may be required.

In conclusion, a low GI diet for women diagnosed with GDM is safe, well tolerated and sustainable. A low GI diet significantly reduces the need for the use of insulin without compromise of obstetric or fetal outcomes.

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**Conflict of interest** JBM is a co-author of The New Glucose Revolution book series (Hodder and Stoughton, London: Marlowe and Co, New York; Hodder Headline, Sydney and elsewhere), President of the GI Foundation, a non-profit GI-based food endorsement program in Australia and Director of the University of Sydney GI

testing service. RGM, MB, MW and PP declare no conflict of interest relevant to this paper.

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**Table 1.** Baseline characteristics of the women (mean  $\pm$  SEM).

	Low GI n = 31	High GI n = 32	P <sup>1</sup>
Age in years	30.8 $\pm$ 0.7	31.3 $\pm$ 0.8	0.68
Weight in Kg ( at enrolment)	83.1 $\pm$ 3.2	86.9 $\pm$ 3.6	0.43
BMI (kg/m <sup>2</sup> ) (at enrolment)	32.0 $\pm$ 1.2	32.8 $\pm$ 1.4	0.68
Parity	0.84 $\pm$ 0.17	0.78 $\pm$ 0.18	0.82
Oral GTT <sup>2</sup> (mmol/L)			
Fasting glucose	4.6 $\pm$ 0.1	4.7 $\pm$ 0.1	0.49
2 – hour glucose	8.4 $\pm$ 0.2	8.4 $\pm$ 0.1	0.83
Gestational age at entry to study (weeks)	30.3 $\pm$ 0.2	29.9 $\pm$ 0.2	0.23

<sup>1</sup>Comparison of low GI group with high GI group, independent samples t-test

<sup>2</sup>OGTT denotes 2 – hour oral glucose tolerance test (75g glucose load)

**Table 2.** Reported dietary intake assessed by 3-day food record at baseline and the final visit (mean  $\pm$  SEM)

	Low GI n = 31	High GI no insulin n=13 (final 12)	High GI to low GI n=19 (final 18)	P <sup>1</sup>	P <sup>2</sup>
Energy (cal)					
Baseline visit	1994 $\pm$ 72	1932 $\pm$ 146	1914 $\pm$ 88	0.50	0.91
Final visit	1713 $\pm$ 66	1664 $\pm$ 79	1651 $\pm$ 73	0.63	0.91
change (P <sup>3</sup> )*	-281 $\pm$ 79 (0.001)	-251 $\pm$ 140 (0.10)	-262 $\pm$ 119 (0.042)		
Protein (%E)					
Baseline visit	18.4 $\pm$ 0.6	20.9 $\pm$ 1.3	21.7 $\pm$ 1.2	0.009	0.64
Final visit	23.9 $\pm$ 0.7	23.5 $\pm$ 0.8	24.4 $\pm$ 0.7	0.51	0.41
change (P <sup>3</sup> )	+5.5 $\pm$ 0.9 (<0.001)	+2.2 $\pm$ 1.1 (0.070)	+2.7 $\pm$ 1.2 (0.041)		
Carbohydrate (%E)					
Baseline visit	45.0 $\pm$ 1.0	42.2 $\pm$ 1.1	45.1 $\pm$ 2.0	0.50	0.28
Final visit	36.7 $\pm$ 1.1	37.8 $\pm$ 1.1	35.1 $\pm$ 1.5	0.80	0.21
change (P <sup>2</sup> )	-8.3 $\pm$ 1.1 (<0.001)	-4.3 $\pm$ 1.3 (0.006)	-10.4 $\pm$ 2.5 (<0.001)		
Fat (%E)					
Baseline visit	31.7 $\pm$ 0.8	32.5 $\pm$ 1.3	31.7 $\pm$ 1.7	0.81	0.74
Final visit	33.4 $\pm$ 1.1	34.0 $\pm$ 1.2	34.5 $\pm$ 1.8	0.57	0.79
change (P <sup>3</sup> )	+1.7 $\pm$ 1.0 (0.11)	+1.6 $\pm$ 1.7 (0.36)	+3.0 $\pm$ 2.2 (0.19)		
Fiber (g)					
Baseline visit	25.4 $\pm$ 1.3	23.1 $\pm$ 1.2	24.0 $\pm$ 1.5	0.30	0.66
Final visit	25.6 $\pm$ 1.3	22.9 $\pm$ 1.1	22.3 $\pm$ 1.6	0.13	0.77
change (P <sup>3</sup> )	+0.3 $\pm$ 1.4 (0.86)	+0.3 $\pm$ 1.5 (0.84)	-1.9 $\pm$ 1.7 (0.28)		

<sup>1</sup>Comparison of low GI group with high GI group (high GI groups combined).

<sup>2</sup>Comparing those who changed to low GI diet with those remaining on High GI

<sup>3</sup>Comparisons from baseline to final visit (\* for those with baseline and final visits only).

**Table 3.** Glycemic Index at all visits

	Low GI group <b>n = 31</b>	High GI group Did not meet criteria for insulin use <b>n = 13</b>	High GI group Met criteria for insulin use and changed to Low GI <b>n = 19</b>	P <sup>1</sup>	P <sup>2</sup>
Baseline visit	57.3 ± 0.9	57.9 ± 1.5	57.4 ± 1.2	0.83	0.79
Visit 2	49.2 ± 0.9 *	56.9 ± 1.1	57.9 ± 1.0	<0.001	0.53
Visit 3	48.7 ± 0.9*	58.2 ± 0.7†	52.2 ± 1.4‡	<0.001	<0.001
Final visit	48.0 ± 0.9	56.0 ± 1.1†	49.6 ± 1.1‡	0.018	<0.001
Change baseline to final visit and p- value	-8.4±1.0(<0.001)	-1.5 ± 1.6(0.38)	-7.9 ± 1.1(<0.001)		

\*n=30 †n=12 ‡n=18

p<sup>1</sup>= comparison of Low GI to High GI groups (combined).

P<sup>2</sup>= comparing those who changed to low GI diet with those remaining on High GI

**Figure 1.** Flow chart of the number of women in each diet group and the number requiring insulin.

