Prevention of Gestational Diabetes

Feasibility issues for an exercise intervention in obese pregnant women

LEONIE K. CALLAWAY, FRACP, PHD[1,2]
PAUL B. COLDITZ, FRACP, FRCPCH, PHD[3,4]
NUALA M. BYRNE, PHD[5,6]
BARBARA E. LINGWOOD, MSC, PHD[3,4]
INGRID J. ROWLANDS, PHD[7]
KATIE FOXCROFT, RN[8]
H. DAVID MCINTYRE, FRACP[9]
FOR THE BAMBINO GROUP*

OBJECTIVE — To examine the feasibility of an individualized exercise program to prevent gestational diabetes mellitus (GDM) in obese pregnant women.

RESEARCH DESIGN AND METHODS — The study was a pilot randomized controlled trial with obese pregnant women (intervention group, individualized exercise program [n = 25]; control group, usual care [n = 25]). Average weekly energy expenditure (MET hours per week and kilocalories per week) of exercise-specific activity was assessed during pregnancy using the Pregnancy Physical Activity Questionnaire. Fasting glucose and insulin and homeostasis model assessment of insulin resistance (HOMA-IR) were assessed at baseline and 20, 28, and 36 weeks' gestation.

RESULTS — Of the women in the intervention group, 16 of 22 (73%) achieved more than 900 kcal/week of exercise-based activity at 28 weeks compared with 8 of 19 women in the control group (42%), P = 0.047. However, insulin resistance (HOMA-IR) did not differ between the groups.

CONCLUSION — This intervention was feasible and prompted a modest increase in physical activity. However, we are not confident that this intervention would be sufficient to prevent GDM.

Diabetes Care 33:1457–1459, 2010

Gestational diabetes mellitus (GDM) is increasing in parallel with overweight and obesity in the obstetric population (1), yet evidence on effective approaches to prevent GDM is lacking. A recent randomized controlled trial (RCT) aimed at modifying nutrition, weight gain, and physical activity in obese pregnant women was not effective in increasing physical activity (2). Based on successful trials in the nonpregnant population (3,4), we aimed to assess the feasibility of individualized, goal-directed exercise intervention in obese pregnant women. Feasibility issues that we address here include implementing the intervention and assessing the efficacy and acceptability of the intervention (5).

RESEARCH DESIGN AND METHODS — Obese pregnant women were recruited at 12 weeks' gestation and followed to delivery with data collection at 12, 20, 28, and 36 weeks' gestation. The intervention group received an individualized exercise program with an energy expenditure (EE) goal of 900 kcal/week, while the control group received routine obstetric care. The primary outcome EE is expressed as *1*) weekly metabolic equivalent (MET) hours and 2) kilocalories per week, measured using the Pregnancy Physical Activity Questionnaire (PPAQ) (6). Fasting insulin and glucose were assessed at each time point, and insulin resistance was estimated using the homeostasis model assessment of insulin resistance (HOMA-IR) (7). A 2-h 75-g oral glucose tolerance test was performed at baseline and 28 weeks. Australasian Diabetes in Pregnancy Society criteria were used for the diagnosis and management of GDM (8). This study was approved by the Royal Brisbane and Women's Hospital Ethics Committee and was registered with the Australian Clinical Trials Registry (ACTRN012606000271505). Further details of the methodology of this study are available in the online appendix at http://care.diabetesjournals.org/cgi/content/full/dc09-2336/DC1.

RESULTS — During the 7-month recruitment period, 50 obese women were randomized to either the intervention group (n = 25) or control group (n = 25), representing a recruitment rate of 12% of all eligible women presenting for maternity care at the Royal Brisbane and Women's Hospital (supplemental Fig. 1, available in the online appendix). There were no statistically significant differences between the intervention and control groups in any baseline variable, although there was a trend toward more frequent early diagnosis of GDM in the intervention group (supplemental Table 1). Women in the intervention group were scheduled for six face-to-face visits during the trial and on average attended four. Further support was provided by email and telephone.

Efficacy

Exercise duration and intensity varied considerably, with a trend toward weekly EE (MET hours per week) being greater for women in the intervention group at 28 and 36 weeks' gestation (Table 1). In the

From the [1]Royal Brisbane Clinical School, Royal Brisbane and Women's Hospital, Brisbane, Australia; the [2]School of Medicine, The University of Queensland, Brisbane, Australia; the [3]Perinatal Research Centre, The University of Queensland, Brisbane, Australia; the [4]University of Queensland Centre for Clinical Research, Royal Brisbane and Women's Hospital, Brisbane, Australia; the [5]School of Human Movement Studies, Queensland University of Technology, Brisbane, Australia; the [6]Institute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane, Australia; the [7]School of Medicine, The University of Queensland, Brisbane, Australia; the [8]Department of Internal Medicine, Royal Brisbane and Women's Hospital, Brisbane, Australia; and the [9]Mater Clinical School, School of Medicine, The University of Queensland, Brisbane, Australia.
Corresponding author: Leonie K. Callaway, l.callaway@uq.edu.au.
Received 21 December 2009 and accepted 22 March 2010. Published ahead of print at http://care.diabetesjournals.org on 31 March 2010. DOI: 10.2337/dc09-2336. Clinical trial reg. no. ACTRN012606000271505, anzctr.org.au.
*The complete BAMBINO Group: Leonie K. Callaway, Paul B. Colditz, Nuala M. Byrne, Barbare E. Lingwood, Ingrid J. Rowlands, Ainsley Groves, Xanthe Sansome, Briony R. O'Connor, Susan Croaker, Katie Foxcroft, and H. David McIntyre.

Table 1—Physical activity and metabolic outcomes at various time points for women in the control group and exercise intervention group

	12 weeks			20 weeks			28 weeks			36 weeks		
	Control	Intervention	*P*	Control	Intervention	*P*	Control	Intervention	*P*	Control	Intervention	*P*
n	25	25		19	21		19	22		16	19	
MET h/week [median (IQ range)]	6.7 (7.5^2)	9.7 (10.12)	0.23	9.9 (22.5)	16.9 (22.2)	0.16	7.5 (14.1)	15.0 (11.2)	0.067	2.8 (9.0)	9.6 (11.0)	0.05
>900 kcal/week [*n* (%)]	7 (28%)	10 (40%)	0.37	9 (47%)	15 (71%)	0.12	8 (42%)	16 (73%)	0.04	5 (31%)	10 (53%)	0.2
HOMA-IR [mean (SD)]	2.49 (1.04)	2.74 (1.72)	0.73	2.21 (1.0)	2.13 (1.68)	0.40	3.53 (1.96)	2.89 (1.27)	0.11	3.82 (3.0)	3.04 (1.84)	0.18
Fasting insulin [mean (SD)]	12.42 (5.06)	13.76 (8.94)	0.74	11.42 (4.68)	10.95 (4.52)	0.37	16.78 (7.85)	14.67 (5.85)	0.17	20.28 (10.8)	14.59 (8.51)	0.05
Fasting glucose [mean (SD)]	4.46 (0.47)	4.47 (0.39)	0.55	4.33 (0.40)	4.28 (0.44)	0.35	4.67 (0.54)	4.38 (0.48)	0.03	4.29 (0.66)	4.18 (0.47)	0.29
GDM [*n* (%)]	0 (0%)	3 (12%)	0.07				3 (16%)	5 (23%)	0.57			

*Analyses were repeated by excluding all women with GDM and then by excluding all women with insulin-treated GDM. Results did not materially differ from those presented here. *Note*: It is recommended that an individual achieves at least between 7.5 and 12.5 MET-h/week to meet current exercise guidelines for weekly moderate-to-vigorous intensity activities (15).

intervention group, 16 of 22 (73%) women achieved the predefined exercise target of greater than 900 kcal/week at 28 weeks compared with 8 of 19 (42%) in the control group (42%), $P = 0.047$. The groups did not differ at baseline or at 20 or 36 weeks. There was no difference in HOMA-IR between the intervention and control groups (Table 1). At 28 weeks, fasting glucose was lower in the intervention group than the control group, and at 36 weeks, insulin was lower in the intervention group.

Acceptability

Feedback was obtained from women in the intervention ($n = 20$) and control groups ($n = 16$). All women in the intervention group provided positive comments (e.g., useful nutritional advice, extra care during pregnancy). Women reported difficulty incorporating exercise into their daily routine due to pregnancy symptoms, child care, and work commitments (supplemental Table 2).

CONCLUSIONS— This individualized goal-directed exercise intervention in obese pregnant women met several criteria of feasibility. Recruitment rates were acceptable, implementation was achieved, and women found participation in the intervention acceptable.

There was some evidence of efficacy, with increased physical activity in the intervention group at some time points during pregnancy. Women in the intervention group were achieving sufficient activity at 20 weeks, falling within the exercise guidelines for weekly moderate- to vigorous-intensity activities (9). At 28 weeks, women in the intervention group were significantly more likely to achieve greater than 900 kcal/week of exercise-based activity. However, while the intervention group showed some improvement in fasting glucose at 28 weeks, and fasting insulin at 36 weeks compared with the control group, there were no definitive between-group differences in HOMA-IR. The study was not powered to examine GDM prevalence as an outcome.

There are a number of potential explanations as to why there was no difference seen in insulin resistance, despite some improvement in physical activity. The difference in physical activity between the two groups might not have been sufficient to result in differences in insulin resistance. Randomization was not concealed from the women due to the need for informed consent. Women in the control group voluntarily undertook far more physical activity than predicted (or seen in clinical practice), which resulted in smaller differences between groups than expected. This issue needs careful consideration for future studies. Exercise alone might not be sufficient during pregnancy to affect insulin resistance. It is also possible that HOMA-IR is not the most sensitive way of assessing the impact of exercise on insulin resistance. Although HOMA-IR is regarded as a good measure of overall insulin resistance in pregnancy, it may provide a better reflection of liver rather than peripheral insulin resistance (7), whereas exercise is likely to preferentially reduce peripheral (muscle) insulin resistance.

Given our data, we believe a combined dietary and exercise intervention might have a stronger impact on insulin resistance, and subsequently on the prevention of GDM. This would be supported by a recent study showing the success of a dietary intervention in reducing the deterioration in glucose metabolism in obese pregnant women (10).

While pregnancy may represent an ideal opportunity to initiate lifestyle changes (11), most interventions in pregnancy have not been overly successful (12). Barriers to physical activity (i.e., pregnancy symptoms, child care responsibilities, work commitments) (13) are difficult to address. While this intervention was feasible and prompted a modest increase in physical activity, there is no evidence to suggest that it would be sufficient to prevent GDM.

Acknowledgments— This study was generously funded by a grant from the Royal Brisbane and Women's Hospital Foundation.

No potential conflicts of interest relevant to this article were reported.

The authors thank the BAMBINO group from the Royal Brisbane and Women's Hospital, Brisbane, Australia, for their contribution to the project: Susie Croaker, Dietitian-Nutritionist, Department of Nutrition and Dietetics; Xanthe Sansome, physiotherapist and research assistant; Briony O'Connor, physiotherapist; and Ainsley Groves, exercise physiologist, School of Human Movement Studies, Queensland University of Technology.

The authors also thank the following staff of the Royal Brisbane and Women's Hospital: Alison Barry, Dr. Karin Lust, Dr. Sophie Clarke, Barbara Waters, Kellie Himstedt, Dr. Jon Hyett, and Dr. Lynda Gillen for their support and contribution to the project and the

midwives from the Maternity Out-patient Department, the birth suite, and the labor ward.

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