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Maternal-Fetal Acute Responses to Two Moderate-Intensity Exercise Types: a Randomized Clinical Trial

Abstract

Objective: This study aims to compare maternal and fetal responses during two physical exercise types.

Design: A randomized clinical trial compared 120 pregnant women, gestational age of 35-37 weeks, 56 exercising on a stationary bicycle (Group A) and 64 on a treadmill (Group B).

Methods: Participants were monitored for three 20-minute phases: resting, exercise and recovery. Fetal heart rate (FHR) and maternal heart rate (MHR) were monitored. Glucose and lactate levels were evaluated at rest and during exercise.

Results: After the beginning of exercise, maximum lactate (L) levels were reached at 20 minutes and never exceeded 4 mmol/l. FHR decreased by 22 bpm during exercise in relation to resting values, irrespective of the exercise type (p<0.001). Comparing the exercise types, the incidence of bradycardia after 10' was 23.2% in Group A and 35.9% in Group B (p>0.05), increasing at 20' to 32% and 40.6%, respectively, (p>0.05). The FHR decrease during exercise was accompanied by a simultaneous increase in its variability (p<0.001), nevertheless a rapid return to resting values was observed shortly after exercise end. Glucose decreased in both groups irrespective of the exercise type (85 mg/dl at rest; 79 mg/dl during exercise and 81 mg/dl during recovery; p<0.001). There were no hypoglycemia cases.

Conclusions: FHR variability increase and the rapid return to resting values after exercise suggests that the FHR fall and the presence of bradycardia during exercise is the fetal physiologic response to blood flow redistribution, with maintenance of fetal well-being.

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Keywords

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Introduction

Physical exercise is currently encouraged during pregnancy as a strategy for promoting health and preventing diseases such as diabetes and obesity [1, 2]. The American College of Obstetricians and Gyne-cologists (ACOG) and the Royal College of Obstetricians and Gynaecologists (RCOG) recommends that women with no medical contraindications should perform moderate exercise [1, 3]. Nevertheless, a Cochrane systematic review concluded that the data available at the present time are insufficient to enable any conclusions to be reached in respect to the risks and benefits to the pregnant woman and fetus [1, 4].

The exercise effects on pregnant woman, such as the increases in heart rate, blood flow [5, 6] and ventilation per minute, and the reduction in respiratory reserve [7], have already been thoroughly investigated. Nevertheless, when the focus is the fetus, there are important gaps in the available knowledge, principally with respect to the potential for reduction in uteroplacental flow and its consequences and the decrease in glucose levels. Previous studies have shown a reduction in fetal heart rate (FHR) and an increase in the incidence of bradycardia [8, 9], as well as a reduction in glucose levels [10, 11], however, results remain contradictory [12, 13].

Therefore, with the acute changes that may occur in response to exercise during pregnancy concurrently with the pregnancy effects itself, this study aims to evaluate maternal and fetal responses to acute moderate-intensity exercise, in previously sedentary pregnant women, in two ways: regardless the exercise type and also comparing two physical exercise types (treadmill and stationary bike).

Methods

This randomized clinical trial compared two groups of pregnant women: one group exercising on a treadmill and the other on a stationary bicycle. Pregnant women receiving care in the municipality of Campina Grande, Paraíba, Brazil were selected. The protocol was approved by the internal review board of the State University of Paraíba (CAAE 0195.0.133.000-11) and registered at Clinical Trials (<u>www.clinicaltrials.gov</u>) under reference NCT01383889.

The inclusion criteria consisted of: a single pregnancy, live fetus, gestational age of 35-37 weeks and having been previously sedentary. Sedentariness was defined as metabolic equivalent tasks (MET) <1.5, which is a caloric expenditure estimate meter. Physical activity level was evaluated using the Pregnancy Physical Activity Questionnaire (PPAQ) [14]. Smoking, chronic diseases, conditions that affect cardiorespiratory function, any physical handicap that limited the performance of physical exercise, arterial hypertension, gestational diabetes, placenta previa, premature labor, bleeding in the third trimester, fetal growth restriction, oligohydramnios, fetus with centralization of blood flow, known fetal abnormalities or a medical contraindication to performing physical exercise constituted exclusion factors.

Sample size was calculated using OpenEpi software, version 2.3.1, based on the following parameters obtained from a pilot study involving 34 women randomized to the stationary bicycle group (n = 18) or to the treadmill group (n = 16): an incidence of fetal bradycardia of 33.3% in the bicycle group compared to 62.5% with the treadmill. For a power of 80% and a 95% confidence interval, 104 women would be required to show this difference. Predicting possible losses, this number was increased to 120 women. The incidence of bradycardia was selected as the basis for calculating sample size, since this is a primary outcome with important repercussions for the fetus.

Pregnant women with gestational age <34 weeks were submitted to ultrasonography to confirm gestational age. At this time, the objectives of the study were explained and the patient was instructed to return at 35-37 weeks of pregnancy if she was interested in participating in the study. Those who

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returned for the scheduled visit were once again submitted to ultrasonography to confirm fetal vitality, and the inclusion and exclusion criteria were applied. If the women fulfilled these criteria and agreed to participate in the study, they were invited to sign an informed consent form.

Next, each consenting woman was randomized to one of the two groups: treadmill or stationary bicycle. Randomization was performed according to a list of random numbers generated by Random Allocation Software, version 1.0 (Isfahan, Iran) by an investigator who was not involved in the data collection and who was responsible for preparing the numbered, opaque, sealed envelopes containing the information regarding group assignment.

Due to the type of intervention, it was impossible for the investigators and subjects to be blinded; however, the evaluators of the outcomes were blinded, as were those responsible for the statistical analysis. The CONSORT guidelines were applied throughout this study [15].

Despite the moderate-intensity exercise practice for 30 minutes or more, for previously active pregnant women, be recommended by ACOG [1], it was carried out the exercise in a shorter duration, 20 minutes, because this study involved a sedentary pregnant population.

Maternal heart rate (MHR) was maintained between 60% and 80% of maximum heart rate corrected for age [16], and recorded continuously using a Polar heart rate monitor (Model S120, Kempele, Finland). Using the Borg scale, ratings of perceived exertion of 12 to 14, denoting "somewhat hard", were applied [17]. Lactate levels were measured at baseline (resting) and then every five minutes during exercise by collecting 25 μ l samples of arterialized earlobe blood. Maximal effort exercise was not performed. The women were supervised by physical education instructors and physiotherapy and medical students specifically trained for this purpose.

The pregnant women were submitted to cardiotocography (Sonicaid 8002) based on the Dawes-

Redman criteria to monitor FHR. Monitoring was performed over a 60-minute period divided into three periods of 20 minutes: resting, exercise and recovery. In the resting and recovery periods, the women remained in the dorsal decubitus position at an angle of 45 degrees. After each 20-minute segment, computerized analysis was performed. The following parameters were recorded over the three periods: FHR, fetal heart rate accelerations, decelerations and short-term variability (cardiotocography), and MHR (heart rate monitor). Exercise duration (20 minutes) was based on the minimum time required for FHR to be adequately evaluated. Fetal heart rate was evaluated every 10 minutes (mean FHR and the frequency of bradycardia and tachycardia at 0, 10 and 20 minutes after resting, exercise and recovery) and the variability every 20 minutes (0 and 20 minutes after resting, exercise and recovery).

A fetal medicine specialist obtained the estimated fetal weight using a Voluson 730 Expert ultrasound device (GE Medical Systems, Milwaukee, WI, USA) with a 2-7 MHz convex transducer. The fetuses were then classified in accordance with their estimated weight for gestational age [18].

The women completed a questionnaire regarding their socioeconomic and obstetric data. Weight was measured to the nearest 0.1 kg using a Tanita digital scale (Tokyo, Japan) and height was measured using a Seca stadiometer (Chiba, Japan). Body mass index (BMI) was calculated using the following formula: weight (kg)/height (m)², and then classified in accordance with Atalah's criteria for gestational age into: underweight, normal weight, overweight or obese [19].

The primary variables evaluated were: baseline FHR (mean FHR and the incidence of bradycardia and tachycardia), FHR accelerations, decelerations and short-term variability. Bradycardia was defined as FHR < 110 beats per minute (bpm) and tachycardia as FHR > 160 bpm for a minimum period of 10 minutes. Deceleration and acceleration were de-

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fined as a decrease or increase, respectively, in FHR of 15 bpm for at least 15 seconds [20]. Other factors evaluated included sociodemographic and obstetric characteristics, maternal anthropometry (weight, height and BMI), fetal anthropometry (estimated weight), and MHR, lactate and glucose levels (with hypoglycemia being defined as glucose levels < 40 mg/dl) measured throughout cardiotocography.

Statistical analysis

The MedCalc software program, version 12.4.0, was used for the statistical analysis. The Kolmogorov-Smirnov test was used to verify whether the distribution of the numerical variables was normal. FHR and MHR, FHR accelerations, decelerations and variability were analyzed as discrete variables. Lactate and glucose levels were evaluated as continuous variables. A bivariate analysis was performed using the chi-square test of association or Fisher's exact test, as appropriate. Initially, the data analysis was conducted with the 120 pregnant women, irrespective of the type of exercise performed, in order to evaluate the overall response to exercise, comparing the three periods: prior to, during and following exercise.

Next, repeated-measures analysis of variance was carried out to compare changes in FHR and its variability, in MHR and in glucose and lactate levels prior to, during and following the practice of physical exercise on a treadmill or stationary bicycle. Since this was a longitudinal study, sphericity was assumed and the p-value for time by intervention interaction was calculated.

A paired t-test was also carried out to compare pre- and post-exercise values, and an analysis was conducted of the difference in the measurements obtained on the treadmill and on the stationary bicycle (MHR and FHR, glucose and lactate) at the different moments evaluated. Analysis was performed on an intention-to-treat basis.

Results and Discussion

A total of 128 pregnant women were selected between December 2011 and December 2012; however, 8 were excluded from the study, resulting in a sample consisting of 120 eligible women. All of these women agreed to participate and all completed the study protocol, with 56 women being randomized to the stationary bicycle group A and 64 to the treadmill group B **(Figure 1)**.

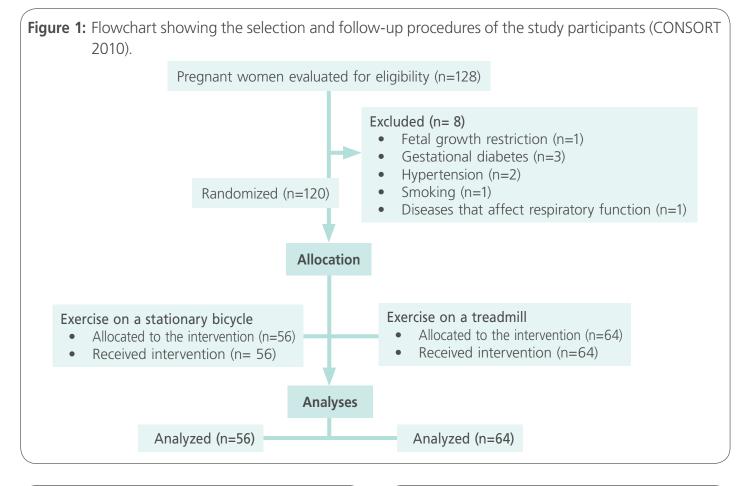
There were no statistically significant differences between the groups with respect to their sociodemographic and obstetrical characteristics or to their BMI. The majority of the women were between 20 and 34 years of age (71.4% of Group A and 67.2% of Group B; p=0.48). Regarding nutritional status, 41.1% of the women in Group A and 50% of Group B were obese (p=0.10). Mean estimated fetal weight was 2,812 ± 305 grams in Group A and 2,753 ± 327 grams in Group B (p=0.32) **(Table 1)**.

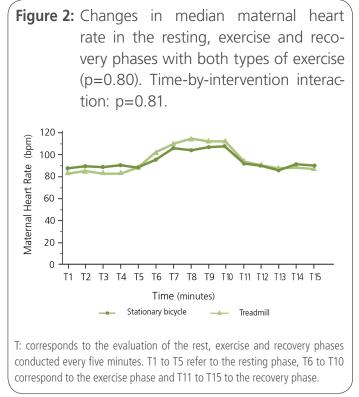
With respect to maternal heart rate, an increase of 28 bpm was detected during exercise in Group A (p<0.001) and 20 bpm in Group B (p<0.001) in relation to resting values, with a return to baseline values immediately following completion of exercise. No statistically significant difference was found when the two groups were compared (p=0.80). Maternal heart rate never exceeded 140 bpm at any time **(Figure 2 & 3)**.

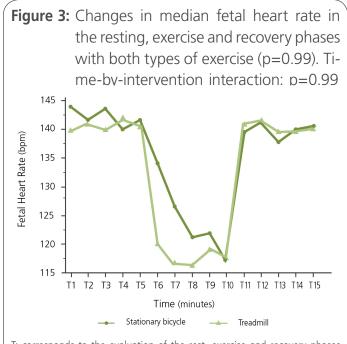
A gradual increase in lactate (L) levels was found following the initiation of exercise, reaching maximum values at 20 minutes (baseline lactate = 0.64 mmol/l \pm 0.17, L5' = 2.19 mmol/l \pm 0.54, L10' = 2.52 mmol/l \pm 0.66; L15' = 2.62 mmol/l \pm 0.56 and L20' = 2.85 mmol/l \pm 0.64, p=0.009). When the two groups were compared, no statistically significant differences were found (p=0.73). Lactate levels never exceeded 4 mmol/l.

During exercise, FHR decreased by 22 bpm in relation to resting values irrespective of the type of exercise performed (p<0.001) **(Table 2)**. When the two types of exercise were compared, no statistically significant differences were found **(Table 3)**.

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T: corresponds to the evaluation of the rest, exercise and recovery phases conducted every five minutes. T1 to T5 refer to the resting phase, T6 to T10 correspond to the exercise phase and T11 to T15 to the recovery phase.

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Table 1.	Baseline characteristics of the pregnant wo-					
	men randomized to physical exercise on a					
	treadmill or stationary bicycle.					

Variable	Stationary bicycle		Treadmill		p-value			
	n	%	n	%				
Age (years)								
< 20	13	23.2	14	21.9	0.48*			
20 - 34	40	71.4	43	67.2				
≥ 35	3	5.4	7	10.9				
Schooling								
\leq 8 years	20	35.7	17	26.6	0.18#			
>8 years	36	43.4	47	73.4	0.16"			
Per capita income								
≤ 1 minimum wage	44	84.6	39	70.9	0.00#			
> 1 minimum wage	8	15.4	16	29.1	0.08#			
Working mother								
Yes	25	45.5	25	40.3	0.05#			
No	30	54.5	37	59.7	0.35#			
Primigravida								
Yes	24	43.6	30	46.9	0.43#			
No	31	56.4	34	56.1				
Body mass index								
Underweight	13	23.2	7	10.9				
Normal weight	13	23.2	10	15.6	o. 4 o #			
Overweight	7	12.5	15	23.4	0.10#			
Obese	23	41.1	32	50				
Fetal weight								
10 th percentile	7	12.5	15	23.4				
50 th percentile	40	71.4	44	68.8	0.06*			
90 th percentile	9	16.1	5	7.8				
*: Fisher's exact test; #: Chi-square test.								

In the resting and recovery phases, none of the fetuses presented with bradycardia. After 10 minutes of exercise, a frequency of bradycardia of 30% was found (95%CI: 15.3 - 47.5%, p<0.0001). At 20 minutes of exercise, the frequency of bradycardia increased to 37% (95%CI: 22.2 - 52.9%, p<0.0001). Comparing the two types of exercise at 10 minu-

tes, the incidence of bradycardia was 23.2% in the stationary bicycle group and 35.9% in the treadmill group (p=0.19). At 20 minutes, the frequency increased to 32% and 40.6%, respectively (bicycle versus treadmill, p=0.43).

The decrease in FHR during exercise was simultaneously accompanied by an increase in its variability (10 cm/s in the resting phase, 21 cm/s during exercise and 9 cm/s in the recovery phase) (p<0.001) **(Table 2)**, with no differences between the different types of exercise (p=0.09) (Table 3).

No statistically significant differences were found when the median accelerations and decelerations were compared in the three periods, irrespective of the type of exercise performed **(Tables 2 & 3)**.

Mean blood glucose level was 85 mg/dl at the end of the resting period, 79 mg/dl at the end of exercise and 81 mg/dl at the end of the recovery period (p<0.001) irrespective of the type of exercise

Table 2. Characteristics of the physical exercise irrespective of the type of exercise.

Variable	Mean	Standard Deviation	p-value				
Fetal Heart Rate							
10 minutes of resting	141	10					
10 minutes of exercise	123	28	< 0.0001				
10 minutes of recovery	141	13					
20 minutes of resting	141	10					
20 minutes of exercise	inutes of exercise 119 29						
20 minutes of recovery	139	11					
Variability							
Resting	10	6					
Exercise	21	13	< 0.0001				
Recovery	9	3					
Glucose							
Baseline	85	15					
10 minutes of exercise	81	13					
20 minutes of exercise	79	13	0.0001				
10 minutes of recovery	81	15					
20 minutes of recovery	81	16					

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Table 3. Characteristics of the physical exercise according to the type of exercise (treadmill or stationary bicycle.

Variable	Treadmill		Stationary bicycle		p-value	
	Mean	SD	Mean	SD		
Fetal heart rate						
10 minutes of resting	143	11	140	9	0.10	
20 minutes of resting	141	10	141	11	0.80	
10 minutes of exercise	127	26	118	30	0.06	
20 minutes of exercise	121	30	118	29	0.37	
10 minutes of recovery	140	15	141	11	0.93	
20 minutes of recovery	139	12	139	9	0.97	
Variability						
Resting	9	3	10	4	0.11	
Exercise	19	14	21	13	0.16	
Recovery	9	3	11	8	0.29	
Glucose						
Baseline	85	17	84	13	0.95	
10 minutes exercise	82	15	81	12	0.91	
20 minutes exercise	80	15	78	12	0.56	
10 minutes recovery	80	15	80	14	0.74	
20 minutes recovery	81	16	81	16	0.87	
SD: Standard deviation.						

(Table 2). During exercise, a gradual reduction in glucose level was noted (85 mg/dl at baseline, 81.2 mg/dl at 10 minutes and 79.1 mg/dl at 20 minutes, p=0.001). There were no cases of hypoglycemia and the changes were similar in the two exercise groups (p>0.05).

Discussion

These results show that moderate physical exercise in healthy, previously sedentary, pregnant women at 35 to 37 weeks of gestational age, induces changes in FHR, FHR variability, MHR and glucose levels, with no statistically significant differences between the two exercise types. The variables returned to preexercise values, shortly after exercise end; however, a trend was found towards a greater decline in FHR and glucose levels and towards a greater increase in MHR and in FHR variability for women exercising on the treadmill.

The 20-minute exercise period could be considered the limitation of the present study, particularly when examining the fall in glucose levels that intensify over time. Nevertheless, this period was sufficient to evaluate other variables such as FHR, the incidence of bradycardia and fetal MHR.

In addition to the greater FHR decrease in the women using the treadmill, a greater incidence of fetal bradycardia was found in this group, which may suggest fetal distress; however, the greater increase in short-term variability, which indicates an efficient adaptation to the exercise [21], and the rapid return to pre-exercise levels suggest a protective fetus mechanism. Furthermore, various studies have evaluated fetal-placental blood flow by Doppler velocimetry, with the majority reporting rapid return of blood flow shortly after exercise end [22, 23]. Unfortunately, it is impossible to evaluate blood flow during exercise, since a tracing cannot be obtained while the woman is in constant movement.

No cases of hypoglycemia were recorded with the glucose level decrease detected, during the exercise phase, which was more evident in the women exercising on the treadmill. A decrease in glucose levels during physical exercise was also found in a study conducted to compare sedentary pregnant women and non-pregnant women submitted to moderate-intensity physical exercise. The authors reported a greater and more rapid decrease in glucose levels in the pregnant women (p<0.05) [11]. Conflicting findings were reported from a study involving healthy pregnant women. Glucose levels decreased significantly to a greater extent in the women who exercised on the stationary bicycle compared to the women who walked on a treadmill for 30 minutes [10]

The increase in MHR and in lactate levels was expected and is considered a normal response to the practice of exercise. None of the women reached a INTERNATIONAL ARCHIVES OF MEDICINE SECTION: EPIDEMIOLOGY ISSN: 1755-7682 2018

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maximum heart rate of 140 bpm or exceeded the maximum lactate level at which exercise is considered aerobic and practiced at moderate intensity (4 mmol/l). Although there is no study to analyze lactate in pregnant women, it does not impact negatively this study, given the other parameters used to evaluate the exercise intensity.

In relation to the fetus, a clinical trial and a longitudinal open study comparing a group of pregnant women who practiced aerobic exercise with a group of sedentary pregnant women, found a reduction in FHR, accompanied by a significant increase in variability [8, 9]. Conflicting results have been reported that range from an absence of any effect on FHR to tachycardia [12, 24, 25]. These contradictory results may be explained by the use of different methodologies.

Monitoring the exercise phase is crucial, as the variables evaluated returned to baseline levels shortly after the end of the exercise. Furthermore, other factors may affect the results, such as the intensity of exercise, the gestational age at which the evaluation was made and the mother's physical fitness level, in addition to other factors that have yet to be studied in depth such as fetal and maternal weight [8].

The strong points of the study include the randomized clinical trial design; the use of computerized cardiotocography, eliminating any trends resulting from interobserver differences; the standardization of gestational age, minimizing the interference caused by immaturity of the central nervous system in the variables evaluated; the physical exercise phase inclusion in the period during which the variables of interest were monitored; and, principally, the comparison between two exercise types, since no consensus yet exists on which exercise is better adapted to this population.

The results reveal the safety of moderate-intensity exercise in healthy pregnant women due to: the increase in FHR variability, the rapid return to preexercise values and the glucose decrease to maintenance levels within safe limits. These findings probably occur by physiological adaptation of the fetus to the visceral reduction flow due to exercise, without compromising the fetal well-being. In addition, the fall in glucose levels suggests that the physical exercise practice as non-drug therapeutic in women with elevated glucose levels may be beneficial. Further studies, on previously active pregnant women and in women with diseases like diabetes and pre-eclampsia, should be supported. Thus, the exercise practice, even in previously sedentary pregnant women should be encouraged.

Clinical Trial Registration

ClinicalTrials.gov, <u>www.clinicaltrials.gov</u>, NCT01383889.

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