Study Title: The impact of Peak Exercise on Pregnancy-induced Dyspnea

Abstract:
Dyspnea is a common but poorly understood complaint of pregnant women. It typically begins in the first or second trimester between week 19 and week 31. Typically, dyspnea of pregnancy is described as a sense of difficulty getting a deep breath, air hunger, or a sense of increased effort. Previous studies examining the relationship between exercise and gestational dyspnea have been inconclusive, possibly because exercise responses were examined at less than 70% of the maximum heart rate. To date, no published studies have reported the effects of strenuous exercise on normal respiratory responses and potential pulmonary function limitations in normal pregnancy. In the proposed study, the use of sensitive and accurate measurements during maximal maternal exercise will provide new insights into the contributions of pregnancy-induced changes in respiratory mechanics and ventilatory limitations to exercise performance in late gestation. The purpose of the proposed study is to examine the interactive contributions of pregnancy-induced changes in respiratory mechanics and the drive to breathe in the development of gestational dyspnea (difficulty breathing). Hypothesis: Restrictive ventilatory mechanics limit exercise tolerance in some but not all healthy pregnant participants. The incidence of mechanical ventilatory limitation will be significantly higher in participants classified as dyspneic.

Method:
Mechanical and perceptual responses to maximal exercise testing will be compared in healthy, normally active pregnant women classified as ‘dyspneic’ or ‘non-dyspneic’. A group of age and activity-matched healthy non-pregnant female controls will also be recruited. Beginning in their 16th week of pregnancy and continuing with once/week sessions until their 37th week of pregnancy, participants’ blood pressure, heart and lung function, and other measures related to breathlessness (e.g. blood gases, circulating hormones) will be assessed. Respiratory function and self-report of breathing difficulty will be measured before, during, and after riding on a stationary bicycle to maximum capacity. Fetal health will be monitored by a fetal heart monitor during the test sessions. Controls will be tested for the same period of time and the same frequency of sessions.

Inclusion and Exclusion Criteria:

Pregnancy Group
- Minimum of 20 - maximum of 50 pregnant women in their 16th week of pregnancy at the date of enrolment in the study
- All participants need to meet the criteria of being ‘normally active’ for six months prior to enrolling in the study and not have any illness or physical impairment that would interfere with their normal activities
- All participants need to have a referral from their obstetrician indicating that they are able to engage in exercise that would normally be recommended for pregnant women

Control Group
- Minimum of 20 - maximum of 50 non-pregnant women who are matched to the pregnancy group for age and activity-level
- All must be at least 18 years of age and non-smokers

Assessment of Risks
Engaging in peak exercise during this study may pose some risks to participants – see page 2. Also attached is a list of safety precautions the research team will take to off-set these risks.

Assessment of Benefits
- copies of written materials on diet, aerobic exercise, muscular conditioning exercises and exercise safety will be provided to all participants
- presence of an obstetrics/nursing specialist throughout the study will provide pre-natal counselling re: appropriate nutrition and exercise during pregnancy, upon request
- the fetal monitoring procedures utilized in this study may provide helpful information for the medical monitoring of the participants’ pregnancies. For example, late gestation ultrasounds, not typical of standard care, may reveal unanticipated issues that require intervention (e.g. low fetal weight, reduction in amniotic fluid, placenta previa, etc.)

Incentives:
All participants will receive reimbursement for expenses incurred as a result of participation in this study (e.g. travel, parking, childcare) up to $10 per hour. In addition all participants will receive 10 coupons that can be redeemed for one dollar off the purchase price of a box of Dr. Cooke’s “Thriving Instant Breakfast” product – a recommended meal supplement for active adults. The product can be purchased and coupons redeemed in the lab after each testing session.

Data Security:
Tests involving blood and fetal health will initially require the participation’s names and health insurance coverage information. All identifying information will be replaced in the data file with alphanumeric codes. The key to this code will be kept in an encrypted digital file by the principal investigator. Personal health information collected during the initial screening process will be used to determine participants’ eligibility for the study. Assessments of pulmonary functioning and fetal health before, during, and after the two lab testing sessions will be linked to participants’ subjective rating of breathing difficulty for data analysis. No identifying information will be linked to these measures. Data will be stored in hard copy and in digital files. Research assistants and medical personnel will be advised to never discuss participants by name. All data will be de-identified and/or coded at the earliest opportunity.

Dissemination
The results of the analysis will be submitted for publication to the appropriate peer-reviewed journal.
Assessment of Risks

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Risks During Pregnancy:

1. Fetal Bradycardia (low fetal heart rate). When the fetus is exposed to reduced blood flow and reduced oxygen levels, its heart rate can slow down below the normal range. This could occur in strenuous exercise because blood is diverted to the mother’s exercising muscles and away from the pregnant uterus. This is a normal protective reflex which helps the fetus to conserve oxygen. There is no harm to the fetus unless bradycardia is prolonged and severe. Fetal bradycardia following material exercise has not been associated with any abnormal pregnancy outcomes.

2. Premature labour. It has been suggested that hormones released with heavy exercise could cause the uterus to contract and bring on premature labour. However, recently published studies do not support the idea that strenuous exercise causes premature labour. Regular exercise may even help to prevent premature labour (Clarke, 2001).

3. Hypoglycemia (low blood sugar). Some studies have reported that blood sugar levels can fall temporarily after sustained strenuous exercise in late pregnancy. When this happens the participant may feel nervous, cold, or develop a mild headache for a short time period. Glucose supply to the fetus may also be temporarily reduced.

Risks for all participants:

1. Breathing tests: Major discomfort is unusual during breathing tests. However, some discomfort (e.g. shortness of breath) may be experienced. Some people experience headache and/or a sense of dizziness as a result of these tests - these effects are usually temporary.

2. Exercise test: Strenuous exercise is associated with a risk of transient abnormal blood pressure responses or disturbances in heart rhythm. Exercise can also trigger a heart attack or other serious heart problems in persons with heart disease. This is very rare in active, non-smoking, apparently healthy young women.

3. Rebreathing procedures: The increased ventilation associated with this procedure may result in temporary discomfort such as dizziness, light-headedness or fainting. It is expected participants will experience a heightened desire to breathe and an associated sensation of breathlessness as the test proceeds. If at any time it becomes more uncomfortable than the participant can tolerate the procedure will be discontinued.

Safety Precautions:

1. All participants who enter the study will be healthy young women, who are non-smokers, have no contraindications to exercise in pregnancy and have been normally active during the six month period prior to involvement in exercise testing.

2. During the week immediately before the first lab visit, pregnant participants will undergo an ultrasound evaluation to estimate fetal health and to verify that they are experiencing a normal pregnancy. With their physician or midwife’s permission these tests will be ordered by our medical monitor, Dr. Houli Bahto and conducted at the Fetal Assessment Unit of City Hospital.

3. An obstetric nurse specialist will be present during the second lab visit to evaluate the rebreathing test and to take blood for the measurement of blood gases, and circulating gestational hormones. This nurse is well trained in blood taking and in fetal monitoring procedures. He will be responsible for recording and monitoring fetal heart rate patterns before, during, and after the rebreathing tests involving pregnant participants. If an abnormal pattern is observed the tests will not be allowed to continue.

4. Participants will be asked to consume a standard meal (Thrive Instant Breakfast) provided by the investigators 1-2 hours prior to the lab visit involving exercise testing to minimize the risk of low blood sugar.

5. Warm-up and cool-down procedures will be used to safeguard the comfort and safety of all participants during the exercise test.

6. If a participant develops obstetric or other health problems or if any information becomes available to suggest that is dangerous to continue in the study, she will be immediately withdrawn from further participation.