Tittle: A Pilot Study: To compare physical activity after a normal spontaneous or cesarean delivery by use of a Actigraph GT3X

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1. Purpose/Specific Aims

This study aims to determine the average level of physical activity using average step counts and daily MET min^{-1} following vaginal and cesarean delivery through use of Actigraph GT3X (a fitness tracker).

1.1 Objectives

The main objective of the study is to determine the average level of physical activity using mean daily steps and daily MET min^{-1}, in women post vaginal and cesarean delivery.

1.2 Hypotheses

The Actigraph GT3X will determine physical activity and step counts and these will be greater in women following vaginal delivery compared to cesarean delivery in a 48 hour period.

2. Background and Significance

Cesarean delivery is the most common surgery performed in the United States.[1] Despite this fact, there is a paucity of literature looking into the implementation of enhanced recovery after surgery (ERAS) for patients undergoing this type of surgery. ERAS protocols have shown to improve recovery from surgery, decreasing complication and hospital length of stay.[2] The pathway for enhanced recovery targets improving [3] factors that have been associated with increased hospital length of stay and complications. These factors are pain, immobilization and postoperative ileus. These factors, many times are inter-related. A patient in pain would tend not to ambulate as this may exacerbate the pain and discomfort. In order to alleviate pain, the patient would most likely receive an opioid for pain management and these medications are known to have undesirable side effects such as nausea, vomiting, sedation, respiratory depression, constipation and urinary retention. All of these adverse effects (AEs) may lead to complications or increased hospital length of stay.

To the best of our knowledge the average level of physical activity (PA) of parturients recovering from a cesarean delivery or after a normal spontaneous vaginal delivery (NSVD) remains unknown. Taking in consideration that parturients are in a hypercoagulable state and that obstetric venous thromboembolism (VT) is one of the most common causes of maternal morbidity and mortality, ambulation is of utmost importance to anesthesiologists as well as obstetricians.[3,4] In order to promote mobility, first we need to learn the average parturients level of physical actity in the immediate post-partum period and up to 48 hours after delivery. This information may help us promote mobility in the immediate postpartum period, particularly for those that underwent a cesarean delivery since they are at higher risk of VT.[4]

Given the lack of knowledge regarding the physical activity level of parturients in the postpartum period we have designed a pilot study to objectively measure their PA. Patients having a normal spontaneous vaginal delivery will serve as our control group. These patients are going through the same physiologyic changes that their counterparts (CD patients) are going through, the only difference being the stress of surgery in the CD group.The use of Fitness trackers (i.e Fitbit(R), Actigraph GT3X +) has been used to measure and promote physical activity in a cardiac rehabilitation population, as well as in parturients self-identified as inactive.[5,6] We intend to use the Actigraph GT3X+ to measure the level of physical activity of 50 parturients (25 NSVD and 25 post CD). The information obtained, we expect, will help us tailor the anesthetic/analgesic management of parturients in such a way that promotes early ambulation and recovery. We estimate that we need approximately a total of 50 patients, 25 per group to assess if there is a difference in the level of PA between parturients after a NSVD or CD. We will aim to recruit 60 patients per group to account for missing data, protocol violations, equipment malfunction or patients drop outs.

3. Research Design and Methods

This will be a multicenter pilot, prospective study aimed at measuring the physical activity (PA) of American Society of Anesthesiologists (ASA) Classification I and II women aged 18 years and older, after a normal spontaneous vaginal (NSVD) or cesarean delivery (CD). Subjects will be ASA I and II women aged 18 years and older, knowing to have had either a NSVD or CD (under neuraxial anesthesia). After delivery, and assuring that mother and baby are stable, patients will be approached by a member of the study team to discuss the study and obtain informed consent. After obtaining informed consent, patients will be divided into Two (2) groups depending on the mode of delivery. Group 1 will be NSVD and group 2 will be CD patients. Patients will be provided with a fitbit- based Actigraph GT3X + hardware, 6 hours after delivery. Patients will be evaluated every 12 hours after delivery for a period of 48 hours. During these evaluation points, pain (visual analogue scores), factors affecting mobility, and level of satisfaction with their analgesia will be assesed. After 48 hrs the Actigraph GT3X + will be interrogated and objective data, such as mean daily steps and daily MET min^{-1}, will be obtained using the aforementioned software.

3.1. Duration of Study

One year

3.2 Study Sites:

University Hospital-Newark, New Jersey

The George Washington University School of Medicine and Health Sciences, Washington DC
Yale, New Haven Hospital

3.3 Sample Size Justification

This study has been designed as a pilot study. Sixty subjects will be enrolled to account for subject withdrawal, lost data, protol violation. The investigators plan to analyze 50 subjects (25/per group).

3.4 Subject Selection and Enrollment Considerations

The study subjects will be American Society of Anesthesiologists (ASA) classification I and II women aged 18 years and older, knowing to have had either a NSVD or CD using a neuraxial analgesia/anesthesia technique.

3.5.1 Inclusion Criteria

The study subjects will be ASA I and II women aged 18 years and older, knowing to have had either a NSVD or CD using a neuraxial analgesia/anesthesia technique.

3.5.2 Exclusion Criteria

History of chronic pain
Recent use of opioids (other than postpartum)
Emergency case requiring general anesthesia (GA) or conversion to GA
BMI > 45
Need to perform more extensive surgery (i.e Hysterectomy)
Need for the neonate to be admitted to NICU (This will prompt mothers to walk more frequently, and longer distances to visit the baby)

3.5.3 Subject Recruitment

Patients will be recruited after a known NSVD or CD. Patients will be approached after assuring that both the parturient and the neonate are stable. The patient will be recruited within the first 6 hrs after delivery.

3.5.4 Consent Procedures

Informed consent will be obtained by one of the investigators after assuring maternal and fetal wellbeing. The parturient will be approached within the first two to six hours after delivery. A thorough explanation of the protocol will be given by one of the investigators.

3.5.5 Subject Costs and Compensation

Subjects will not be compensated for their participation in the study.

3.6 *Chart Review Selection*

The study data will be collected from the subject as well as a review of the subjects Medication Administration documents found in EPIC.

4. Study Variables

4.1 Independent Variables or Interventions

Independent variables: Demographic and labor data (patient age, ethnicity, height, weight, body mass index (BMI), gravity, parity, time of delivery, mode of anesthesia or analgesia, mode of delivery, post-partum analgesia (iv or po analgesia), number of previous CD and prior abdominal surgery).

Interventions: After obtaining informed consent, patients will be assigned to either the NSVD or CD group. Patients will be provided with a fitbit- based Actigraph GT3X + hardware, 6 hours after delivery. Physical activity will be objectively measured using the Actilife software and fitbit- based Actigraph GT3X + hardware. Physical activity will be measured as mean daily steps and daily MET min^{-1}. This data will be obtained at 48 hours after NSVD or CD and will be compared at the 12 hour, 24 hour, 36 hour, and 48 hour time points.

4.1.1 Drug or Device Interventions

The Actigraph GT3X-BT (Actigraph, Florida, US) is an accelerometer that assesses total body displacement across a vertical plane and determines physical activity levels in the form of activity and step counts. This device has been previously validated.[7]

4.2 Dependent Variables or Outcome Measures

Dependent variables: Factors contributing to immobility (i.e foley catheter), pain scores at rest and with movement will be measured using VAS scores, medications administered and satisfaction with analgesia will be monitored every 12 h for 48 h.

Outcome measures:

Primary: mean average steps and MET min^{-1}

Secondary: Pain and satisfaction scores

4.3 Risk of Harm

This study does not involve any potential risk to the patient. The patients will simply be asked to wear a wrist fitbit-based accelerometer (Actigraph GT3X-BT). At most, it is possible that some patients may develop a rash or mild skin reaction to the wrist band of the aforementioned device.

4.4 Potential for Benefit

The potential benefit from participating in this study includes helping physician to gain knowledge as to the physical activity of parturients immediately postpartum. The knowledge gained may help us tailor our analgesic strategies or simply encourage the parturient to increase their physical activity, particularly after CD as those patients are at higher risk for thromboembolic events.

4. Data Handling and Statistical Analysis

The study data will be collected on the data collection form. Subjects will be assigned a code consisting of a number and letters designating the mode of delivery, the first subject at Rutgers

New Jersey Medical School 1RNJMS-CD or 1RNJMS-NSVD). The first page of the data collection form, which contains limited protected health information (patient name, MRN) will be kept until all data is gathered, then the form will be de-identified by destroying the first page, saving only the subject number. All forms will be securely kept in a locked cabinet in the locked office of the principal investigator at each participating institution. All digital data stored on computers will be on encrypted drives. Only study team participants will have access to the collected data.
There are no specific privacy issues beyond the confidentiality of study data as described above**.**

This will be a pilot prospective study, in which objective physical activity (measured as mean daily steps and daily MET min^{-1}) will be the main primary outcome. Given that this is a pilot study, we estimate that we need approximately a total of 50 patients, 25 per group to assess if there is a difference in the level of PA between parturients after a NSVD or CD. We will aim to recruit 60 patients total to account for missing data, protocol violations, equipment malfunction or patients drop outs.

ANOVA will be used to study variablilty between groups. Kruskal Wallis will be used for averages.

7. Reporting Results

7.1 Individual Results
Expressed in terms of average and standard deviation.

7.2 Aggregate Results

7.3 Professional Reporting
Results maybe presented at one or more of the following Annual Meetings the American Society of Anesthesiologists, International Anesthesia Research Society, the Society of Obseterics and Perinatology. Journal publication may include ***Anesthesiology or Anesthesia and Analgesia.***

8. Bibliography
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