

Summer Student Research Program
Project Description

FACULTY SPONSOR'S NAME AND DEGREE: Vasanti Tilak MD

PHONE: (973) 972 - 5254

DEPARTMENT AND INTERNAL MAILING ADDRESS: Anesthesiology and
Perioperative Medicine; 185 So. Orange Ave, Medical Science Building E-538;
Newark, New Jersey 07103

E-MAIL: tilakva@umdnj.edu

PROJECT TITLE (200 Characters max):

Can blood glucose levels during the perioperative period identify a population at risk for hyperglycemia ?

HYPOTHESIS:

Null hypothesis

(HO): There will be no difference in perioperative blood glucose in non diabetics for examining hyperglycemia.

Alternate hypothesis

(HA): There will be a difference in perioperative blood glucose in non diabetics and we will be able to identify risk factors for hyperglycemia.

PROJECT DESCRIPTION (Include design, methodology, data collection, techniques, data analysis to be employed and evaluation and interpretation methodology)

Surgery performed during general anesthesia induces a stress effect on the body partially through a catabolic energy state. In turn, glucose levels may rise to levels which have been associated with major morbidity (Golden, 1999) and mortality (Ouattara, 2005). While cardiac surgery now typically uses "tight glycemic control" therapies to prevent hyper- and hypo-glycemia in the perioperative and ICU period, major noncardiac surgery and the effects of perioperative hyperglycemia are beginning to emerge. In the Miriam study a high percentage of patients in the control group had intraoperative blood glucose levels over 225. After one hour of surgery: 20%, after two hours: 28%, after three hours: 31% and in the post-anesthesia recovery room: 52%. These levels may be associated with significant post-operative morbidity as shown in the cardiac surgery population.

The authors in this study did not attempt to associate the high glucose levels with patient variables e.g. age, gender, body mass index, co-existing diseases, concurrent medications, type of surgery, post operative pain levels etc. Our plan is to identify population at risk of hyperglycemia during perioperative period. We propose to measure glucose levels in non diabetic patients at predefined intervals during perioperative period. The data will be analyzed to identify patient variables that correlate with perioperative hyperglycemia.

References:

Summer Student Research Program Project Description

1. Ouattara A, et al. Poor intraoperative blood glucose control is associated with a worsened hospital outcome after cardiac surgery in diabetic patients. *Anesthesiology*, 2005;103:687-94.
2. Lattermann R, et al. The anticatabolic effect of neuraxial blockade after hip replacement surgery. *Anesth Analg*, 2005;101:1202-8.
3. Miriam A, Korula G. A simple glucose insulin regimen for perioperative blood glucose control: The Vellore regimen. *Anesth Analg*, 2004; 99:598-602.
4. Golden S, et al. Perioperative glycemic control and the risks of infectious complications in a cohort of adults with diabetes. *Diabetes Care*, 1999; 22(9):1408-14

An informed consent will be obtained before elective surgery. Blood glucose will be tested before going to the operating room by finger stick or by drawing blood during placement of intra venous catheter. Blood samples will be taken at various intervals during and after surgery to test for glucose. Portable glucose meters, similar to those used by diabetics to test their glucose level at home, will be used to measure the glucose levels required by the study protocol. The glucose meter chosen is the Free Style Flash™ manufactured by Abbott Diabetes Care (see attachments for information regarding this meter). Should the subjects' glucose level rise above 120 during the course of the operative procedure than a HbA1C will be done via a device in the Department of Anesthesiology basic science laboratory. The surgical team responsible for the subject will be notified if the subject has an elevated HbA1C. In addition, the subject will be provided a letter by the anesthesia study team to alert their primary care physician to the elevated HbA1C so that they may seek follow up.

This is a prospective clinical study to define the relationships between time profile of glucose control before, during and after surgery with patient variables, surgical variables and anesthetic variables.

Prior to procedure: After obtaining informed consent blood sugar will be measured by glucometer via fingerstick or blood obtained during placement of intravenous catheter.

The following patient information will be recorded:

1. age
2. gender
3. BMI
4. Current medications
5. Concurrent diseases
6. Baseline fasting blood glucose levels (from standard PAT visit lab value on medical record)

During surgery: Anesthetic management as per attending anesthesiologist.

Blood sugar will be measured at following intervals

15 min after induction of anesthesia

15 min after incision

At 15 min intervals during surgery for the first 2 hours followed by 30 min intervals

The following data will be collected:

1. Type of anesthesia

Summer Student Research Program
Project Description

2. Agents used
3. Type and amount of IV fluids
4. Surgical procedure
5. Blood loss

Post Anesthesia Care Unit

Blood glucose will be measured 30 min after admission to recovery room and at one hour for a total of two samples.

The following data will be collected:

1. Numerical pain score (0-10 where 0= absence of pain and 10 = worst imaginable pain)
2. Pain medication

Post Operative Period

On the subjects' 14th post operative day, a member of the study team will telephone the subject to inquire about adverse surgical outcomes. (cardiac, pulmonary, neurological and wound infection requiring admission).

Inclusion criteria:

- Patients 18-80 years of age with no past medical history of diabetes
- Elective surgery

Exclusion criteria:

- Known diabetics (Type I and Type II)
- Pregnant patients
- Cardiac surgery
- Liver transplant surgery

Using logistic regression we will take the baseline blood glucose values, the demographics and the surgical variables (length of surgery, PACU pain levels) and fit a best fit equation to what predicts higher perioperative blood glucose levels. Secondary analyses will include multiple regressions of parametric variables to see, for example, if PACU pain levels are associated with intraoperative glucose changes.

SPONSOR'S MOST RECENT PUBLICATIONS RELEVANT TO THIS RESEARCH:

n/a

IS THIS PROJECT SUPPORTED BY EXTRAMURAL FUNDS?

Yes or No

(IF YES, PLEASE SUPPLY THE GRANTING AGENCY'S NAME)

Summer Student Research Program
Project Description

THIS PROJECT IS: **Clinical** **Laboratory** **Behavioral** **Other**

THIS PROJECT IS CANCER-RELATED

Please explain Cancer relevance

THIS PROJECT IS HEART, LUNG & BLOOD- RELATED

Please explain Heart, Lung, Blood relevance

Since our institution cares for an underserved patient population, many of whom do not have a primary care physician, we feel that our study is particularly helpful in potentially identifying those at risk for diabetes and in some cases alerting those patients who are unaware that they are Type II diabetics.

The most life threatening consequences of diabetes are heart disease and stroke, which strike people with diabetes more than twice as often as they do others. According to statistics provided by the American Diabetes Association, most of the cardiovascular complications related to diabetes has to do with the way the heart pumps blood through the body. Diabetes is also responsible for increasing the rate of atherosclerosis or hardening of the arteries. Heart disease strikes people with diabetes, twice as often as people without diabetes. People with diabetes are twice as likely to suffer strokes and once having had a stroke, are two to four times likely to have a reoccurrence. Deaths from heart disease in women with diabetes have increased 23% over the past 30 years compared to a 27% decrease in women without diabetes. Deaths from heart disease in men with diabetes have decreased by only 13 % compared to a 36% decrease in men without diabetes.

THIS PROJECT EMPLOYS RADIOISOTOPES

THIS PROJECT INVOLVES THE USE OF ANIMALS

PENDING

APPROVED

IACUC PROTOCOL #

THIS PROJECT INVOLVES THE USE OF HUMAN SUBJECTS

PENDING

APPROVED

IRB PROTOCOL # M 0120060208

THIS PROJECT IS SUITABLE FOR:

UNDERGRADUATE STUDENTS
SOPHMORES

ENTERING FRESHMAN
ALL STUDENTS

THIS PROJECT IS WORK-STUDY: Yes or No

WHAT WILL THE STUDENT LEARN FROM THIS EXPERIENCE?

The student will benefit from their participation in a structured research study. They will be exposed to Good Clinical Practice (GCP) which ensures the rights and safety of clinical trial subjects and the integrity of clinical data obtained during the conduct of a clinical trial. The student will have the opportunity to have a comprehensive review of the protocol, participate in subject-investigator interactions, ongoing and risk appropriate

Summer Student Research Program

Project Description

safety monitoring throughout the conduct of the study and assist in data collection, analysis and reporting.

Additional students will benefit from the experience of interviewing the subjects and reviewing the medical history to assess the individual eligibility for inclusion into the study. They will benefit from the experience of spending time in the Operating Room and having the opportunity to witness a variety of surgical procedures and anesthetic techniques.