RESEARCH PROTOCOL

Date	4/6/2022
Title	Evaluation of providing coffee to patients postoperatively to decrease length of stay in the PACU
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Hatton #	18-050

Purpose of Study

The purpose of the study is to determine if providing coffee to patients who self-identify as coffee drinkers postoperatively will decrease the length of stay in the post-anesthesia care unit (PACU). Decreasing the length of stay in PACU for surgical patient is a pertinent outcome. The shorter length of stay can achieve higher patient engagement scores, while simultaneously increasing the productivity of the unit. This is achieved by making more beds available for new patients coming from the operating room (OR). One thought was that coffee would benefit our patients experience through a number of pathways. Initially, the stimulant effect of coffee would create a more alert patient. A more alert patient is more likely to comprehend home care instruction and be ready for discharge earlier. Coffee is often used as a remedy for morning sickness. Ideally the act of drinking coffee or even smelling the coffee may decrease the occurrence of Post-Operative Nausea and Vomiting (PONV) in our patient population. Finally, patients frequently state that the inability to drink their morning coffee is often more difficult than not being able to eat prior to surgery. By allowing those to drink coffee in PACU this would make the patient feel that they are being cared for on an emotional level, in addition to a physical level.

Hypothesis or Research Question

Primary Hypothesis:

Hypothesis 1: Patients who self-identify as coffee drinkers who receive coffee postoperatively will experience a shorter length of stay in the PACU compared to patients who self-identify as coffee drinkers and do not receive coffee postoperatively.

Secondary Hypotheses:

Hypothesis 2: Patients who self-identify as coffee drinkers who receive coffee postoperatively will experience a lower occurrence of postoperative nausea and vomiting in the PACU compared to patients who self-identify as coffee drinkers and do not receive coffee postoperatively.

Hypothesis 3: Patients who self-identify as coffee drinkers who receive coffee postoperatively will report higher patient satisfaction compared to patients who self-identify as coffee drinkers and do not receive coffee postoperatively.

Background

After performing a thorough review of the literature, no studies were found that examined whether there are benefits of drinking coffee for post-operative patients. There have been a few studies that have demonstrated a benefit of three times daily coffee consumption following abdominal surgeries. In a study of 80 patients undergoing elective open or laproscopic colectomy, Muller and colleagues (2012) found that patients who consumed 100mL of coffee three times daily, compared to patients assigned to consume 100mL of water three times daily, had a significantly shorter time to first bowel movement. Similarly, Gungorduk and colleagues (2017) studied 114 patients who were undergoing total abdominal hysterectomy and systematic paraaortic lymphadenectomy and found that compared to a group assigned to drink water, those patients assigned to consume coffee 3 times daily postoperatively, had a shorter time to bowel motility and ability to tolerate food. While these studies demonstrate that coffee consumption was tolerated after surgery, they do not provide evidence about the effectiveness of coffee consumption on length of stay and/or postoperative nausea and vomiting in the PACU.

Theoretically, coffee consumption is associated with increased brain function. “Coffee is also well-known for its positive effects on mental alertness and psychological lift, benefits often attributed to caffeine content. Indeed, frequent low doses of caffeine counter the effects of extended wakefulness” (Taylor & Demming-Adams, 2007). Additionally, Warner and colleagues (2018) state that murine models have demonstrated an enhanced speed of recovery from general anesthesia, however this phenomenon has not been examined in humans. Therefore, Warner’s team (2018) conducted one of the first (if only) studies examining the association between caffeine administration and changes in sedation scores among 151 heavily sedated patients in a PACU. Following administration of IV caffeine, RASS scores increased and no adverse respiratory events were noted following caffeine administration. The data suggested that IV caffeine may enhance speed of recovery from general anesthesia. Warner and colleagues’ study provides preliminary evidence that coffee consumption may increase speed of recovery. Once again, no studies have examined whether providing coffee to patients postoperatively would decrease the length of stay in the PACU compared to not providing coffee.

Research Plan

- **Study Design**

  A randomized, non-blinded, controlled study will be conducted, with two arms. Subjects will be randomized into one of the two following arms:
  - Arm 1: Subjects will receive coffee while in the PACU
  - Arm 2: Subjects will NOT receive coffee in PACU

- **Setting for the study**

The study will take place in the Bethesda North Minimally Invasive Surgery Center. This unit consists of 3 operating rooms and 7 postoperative recovery bays. The team members on this unit provide care for patients undergoing minimally invasive outpatient procedures including (but not limited to) Herniorrhaphy Repairs, Laparoscopic Cholecystectomies, Lipoma Removals, Hysteroscopies, Uterine Ablations, Bladder Slings, Female Sterilization, Breast Reductions and Augmentations, and other Plastic Surgery. There are approximately 10-20 surgeries performed in this setting each day. We are a 3 OR Suite facility with 6 Pre-Op Bays and 7 Recovery Bays.

In April 2022, the Bethesda Surgery Center was added as a second recruitment site. This unit consists of 4 operating rooms and 8 postoperative recovery bays. The team members on this unit provide care for patients undergoing minimally invasive outpatient procedures including (but not limited to) Herniorrhaphy Repairs, Laparoscopic Cholecystectomies, Hemorrhoidectomies, Lipoma Removals, Eye Muscle Repair, Breast Reductions and Augmentations, Abdominoplasty, and other Plastic Surgery. There are approximately 10-20 surgeries performed in this setting each day. We are a 4 OR Suite facility with 6 Pre-Op Bays and 8 Recovery Bays.

- **Participants**

This study will enroll 300 subjects who meet the inclusion/exclusion criteria.

Inclusion criteria:
1. 18 years old or older
2. Admitted to Bethesda North Minimally Invasive Surgery Center or the Bethesda Surgery Center
3. Reports to consume at least one cup of coffee a day for at least 5 days in a week

Exclusion Criteria
1. History of PONV
2. Pre-existing cardiac arrhythmias
3. History of seizure disorder
4. Pregnant

Withdraw Criteria (patients who meet inclusion/exclusion criteria and consent to participate, but then develop one of these criteria, will be removed from the study)
1. Participants in the intervention arm who fail to drink at least 50 ml of coffee
2. Participants in the intervention arm who experience PONV prior to coffee consumption
3. Participants in the control arm who experience PONV prior to or during consenting process (consenting process will stop if patient begins experiencing PONV)

Sample Size Determination: A power analysis was conducted using G*Power (version 3.1.9.2). The primary outcome variable (length of stay) was used with a small-medium

effect size (0.3), power of 0.8, and level of significance 0.05. It was determined that 139 patients would be needed in each group, for a total sample size of 278 patients. Therefore, we plan to enroll approximately 300 patients to allow for missing data and patient withdrawals.

- **Data Collection**

Before the study begins, the study staff will provide education to all of the nurses working in the department involved in patient care. This education will include information about the study design, the intervention, and the inclusion/exclusion criteria.

Patients who meet the inclusion criteria will be approached by a member of the study team. The study team member will describe the study and answer any questions the patient has. If the patient is interested in enrolling in the study, they will be asked to review and sign an Informed Consent Form and a HIPAA Authorization Form. Personal health information, including name and date of birth, are recorded on the informed consent form and/or HIPAA Authorization Form.

After the patient provides written informed consent, the study team member will remove the next envelope out of a box of prefilled and sealed opaque envelopes. The envelope will provide the Subject ID number to be used on all study-related documentation and the study Arm that the patient has been randomized to.

- **Intervention or experimental aspect of the study**

Patients randomized to Arm 1 will receive coffee in a Styrofoam cup at a temperature of 125 degree Fahrenheit or less (Brown & Diller, 2008). Coffee will be offered to the patient in the PACU once the patient's gag reflex has been restored following their procedure. Volume of estimated coffee consumption will be measured using a sample scale (with a maximum of 300mL of coffee offered). Patients randomized to Arm 2 will not be offered coffee while in the PACU.

A data collection form will accompany patient to the PACU designating them as a study participant. Data will be recorded directly on this form and collected by a study team member after the patient is discharged.

Independent variable:

- Whether patient consumed part or all of the coffee in the PACU or not

Dependent variables:

- Primary outcome variable - Patient's LOS in the PACU
- Secondary outcome variables:
  - Whether the patient experienced PONV
  - Patient satisfaction

Potential confounding variables:

- How many minutes after entering PACU patient consumed coffee
- How much coffee patient consumed

- **Statistical Analysis**

Data will be recorded on paper data collection forms with only subject ID and no identifiers. Data from these forms will be entered into a password protected database. Only study team members will have access to the database. No personal information will be entered into the electronic database. Data will undergo range checks when entered into the database, and quality control procedures will be performed to ensure accuracy of the data in the electronic database.

Statistical analyses will be performed using SPSS statistical software. Descriptive statistics (frequencies for categorical data; means and standard deviations and ranges for continuous data) will be used to describe the sample. The following analyses will be performed to address each hypothesis:

Hypothesis 1: Patients who self-identify as coffee drinkers who receive coffee postoperatively will experience a shorter length of stay in the PACU compared to patients who self-identify as coffee drinkers and do not receive coffee postoperatively.

To compare the effects of the intervention, an independent samples t-test will be used to compare mean length of stay in the PACU for patients who received coffee to the mean length of stay in the PACU among patients who did not receive coffee. A level of significance of $\alpha=0.05$ will be used.

Hypothesis 2: Patients who self-identify as coffee drinkers who receive coffee postoperatively will experience a lower occurrence of postoperative nausea and vomiting in the PACU compared to patients who self-identify as coffee drinkers and do not receive coffee postoperatively.

To compare the effects of the intervention, a Chi Square test will be used to compare occurrence of postoperative nausea and vomiting for patients who received coffee to patients who did not receive coffee. A level of significance of $\alpha=0.05$ will be used.

Hypothesis 3: Patients who self-identify as coffee drinkers who receive coffee postoperatively will report higher patient satisfaction compared to patients who self-identify as coffee drinkers and do not receive coffee postoperatively.

To compare the effects of the intervention, an independent samples t-test will be used to compare mean patient satisfaction for patients who received coffee to the mean patient satisfaction among patients who did not receive coffee. A level of significance of $\alpha=0.05$ will be used.

Ethical Considerations

- **Informed consent**

All study staff will complete CITI training. A study staff member will meet with potentially eligible patients and describe the study and answer any questions. If the patient is interested and meets all the inclusion/exclusion criteria, the study staff will review the *Informed Consent Form* and *HIPAA Authorization* and obtain written informed consent. Patients will receive a copy of their signed Informed Consent form and HIPAA Authorization.

Informed Consent forms and HIPAA Authorizations will be stored in a locked cabinet that only study staff will have access to. After the study closes, the signed Informed Consent forms and HIPAA forms will be boxed and sent to off-site storage and securely stored for 10 years. At that time, the hard copy forms will be shredded.

- **Privacy information**

Personal identifiers will not be recorded on data collection forms or the electronic database of final data. Hard copy data collection forms will be stored in locked cabinets that only study staff will have access to. Electronic data will be stored on a password-protected folder on the U drive. Only study staff will have access to the electronic study documents. After data analysis and dissemination is completed, hard copy forms will be boxed and sent to secure storage for 10 years at which time they will be shredded. After data analysis and dissemination, electronic data and forms will be de-identified and transferred to a password-protected flash drive which will be sent to secure storage for 10 years at which time it will be destroyed.

Cost/Budget

There will be no costs to conduct this study and no additional charges to patients.

Estimated Period of Time to Complete Study	
When will study begin?	April 1, 2018
Protocol Development Completed	1 month
Scientific Review	2 weeks
Admin Review Time	2 weeks
IRB Approval	6 weeks
Data collection	3 months
Data analysis	2 months
Presentation development (if applicable)	1 month
Manuscript Development (if applicable)	3 months

Journal submission process (if applicable)	6 months
Study closure	1 month

- **When and how will results be disseminated?**

Results will be disseminated internally to the TriHealth perioperative leadership team and system-wide through the TriHealth Research Council. Results will be disseminated nationally through presentation at a professional organization conference. Finally, results will be disseminated nationally and internationally by publication in a relevant peer-reviewed journal.

References

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