Evaluating the use of peppermint oil for postpartum women with urinary retention

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RESEARCH PROTOCOL

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Title	Evaluating the use of peppermint oil for postpartum women with urinary retention
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Purpose of Study

The purpose of the study is to determine if the use of peppermint oil among postpartum women experiencing urinary retention will increase spontaneous urination and decrease the need for catheterization. Urinary retention is a common occurrence after delivery and can result in discomfort, urinary catheterization, increased risk of postpartum hemorrhage, and increased length of stay. One novel intervention to resolve urinary retention is exposure of the perineum to peppermint oil vapors. This has been studied in four women postoperatively and reported three of the women voided spontaneously after peppermint oil exposure. There were no adverse events reported among these four women (Phillips, 1998). This descriptive study provides preliminary data that peppermint oil could potentially be an effective intervention for urinary retention, but the study had many limitations including a very small sample, a descriptive study without a comparison group, and a heterogenous sample of postoperative women. The current study seeks to build on this by studying the use of peppermint oil among a larger sample of postpartum women experiencing urinary retention using a randomized design.

Hypothesis or Research Question

Hypothesis 1: Postpartum patients with urinary retention who are exposed to peppermint oil will experience a higher frequency of resolution of urinary retention compared to postpartum patients with urinary retention not exposed to peppermint oil.

Hypothesis 2: Postpartum patients with urinary retention who are exposed to peppermint oil will experience a shorter time to spontaneous urination compared to postpartum patients with urinary retention not exposed to peppermint oil.

Hypothesis 3: Postpartum patients with urinary retention who are exposed to peppermint oil will experience an increased volume of spontaneous urine compared to postpartum patients with urinary retention not exposed to peppermint oil.

Hypothesis 4: Postpartum patients with urinary retention who are exposed to peppermint oil will experience a decreased frequency of urinary catheterization compared to postpartum patients with urinary retention not exposed to peppermint oil.

Hypothesis 5: Postpartum patients with urinary retention who are exposed to peppermint oil will experience increased patient satisfaction compared to postpartum patients with urinary retention not exposed to peppermint oil.

Background

Urinary retention is a common occurrence after delivery, resulting in discomfort, pain, and potential need to invasive intervention, including urinary catheterization. Urinary catheterization puts patients at an increased risk for infection, discomfort, and dissatisfaction (Baldini et al., 2009). Anecdotally, peppermint oil vapors have been touted as a noninvasive way to relax muscles and stimulate urination. However, this has not been studied rigorously. Philips (1998) conducted a descriptive study examining the use of peppermint oil vapors in four postoperative women and found that that 3 of the 4 women were able to void spontaneously after being exposed to peppermint oil and no women experienced adverse events. Fryatt and Bell (2020) examined the use of inhaled peppermint oil among 36 pediatric postoperative patients with urinary retention and found a 32% decrease in the need for urinary catheterization among patients who inhaled peppermint oil. While these studies provide interesting preliminary information, a rigorous well-powered randomized trial is needed to truly investigate the use of peppermint oil to stimulate spontaneous urination specifically in postpartum women experiencing urinary retention. The current study seeks to fill this gap.

Research Plan

- **Study Design**

  A randomized controlled study will be conducted, with two arms. Subjects will be randomized into one of the two following arms:

  - Arm 1: Subjects will be exposed to vapor of peppermint oil
  - Arm 2: Subjects will be exposed to vapor of placebo (mineral oil)

- **Setting for the study**

  The study will take place in the Bethesda North Mom Baby Unit. This unit consists of 35 rooms. The team members on this unit provide care for patients following delivery. There are approximately 18 women receiving care on this unit each day.

- **Participants**
  This study will enroll 100 subjects who meet the inclusion/exclusion criteria.

  Inclusion criteria:

  1. 18 years old or older
  2. English speaking
  3. Admitted to Bethesda North Mom Baby Unit
  4. Postpartum
  5. Experiencing urinary retention – defined as meeting at least one of the following criteria:
     - More than 6 hours after delivery or foley catheter removal without being able to spontaneously void
     - Symptomatic urinary retention without being able to spontaneously void
     - Change in fundal height or position without being able to spontaneously void
  6. Bladder scan showing bladder containing 400mL or more urine

  Exclusion Criteria

  1. Allergy to peppermint
  2. Asthma
  3. Active herpes lesions
  4. Seizure disorder
  5. Not able to void in toilet (ex: requiring use of bed pan to void)

  Sample Size Determination: A power analysis was conducted using G*Power (version 3.1.9.2). The primary outcome variable (resolution of urinary retention) was used with a medium effect size, power of 0.8, and level of significance 0.05. It was determined that 44 patients would be needed in each group, for a total sample size of 88 patients. Therefore, we plan to enroll approximately 100 patients (50 randomized to each group) to allow for missing data and patient withdrawals.

- **Data Collection**
  Before the study begins, the study staff will provide education to team members working in the unit 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 and HIPAA Authorization

Form. Name is included on the Informed Consent Document and name and date of birth are included on the HIPAA Authorization.

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. All 100 envelopes will be filled before the start of the study using a 1:1 computerized randomization generator.

- **Intervention or experimental aspect of the study**
  If the patient is randomized to Arm 1 (intervention group), the study nurse will place 2mL of peppermint oil into the urine collection hat that fits into the toilet bowl. Subjects will sit on the toilet exposing their perineum to the vapor of the oil. The perineum will NOT come into contact with the oil directly. After approximately 10 minutes, the nurse will remove the patient from the toilet. If spontaneous urination occurred, the nurse will measure the volume of urine obtained in the hat. The nurse will calculate approximate volume of urine remaining in the bladder (bladder scan volume minus volume of urine in collection hat). If approximate volume remaining in the bladder is 200mL or greater, the nurse will perform a second bladder scan and follow standard practice for urinary retention.

  If the patient is randomized to Arm 2 (control group), the study nurse will place 2mL of mineral oil into the urine collection hat that fits into the toilet bowl. Subjects will sit on the toilet exposing their perineum to the vapor of the oil. The perineum will NOT come into contact with the oil directly. After approximately 10 minutes, the nurse will remove the patient from the toilet. If spontaneous urination occurred, the nurse will measure the volume of urine obtained in the hat. The nurse will calculate approximate volume of urine remaining in the bladder (bladder scan volume minus volume of urine in collection hat). If approximate volume remaining in the bladder is 200mL or greater, the nurse will perform a second bladder scan and follow standard practice for urinary retention.

  The voiding procedure using the oil and urine collection hat will be performed only one time with each participant. The study participants won't be explicitly told which group they were randomized into, but the investigators do not consider the subjects to be blinded to group assignment since the smell of the oil will be detectable.

  A data collection form will be in the randomization envelope. Data will be recorded directly on this form and collected by a study team member after completion of the study.

Independent variable:

- Whether patient sat on toilet for full 10 minutes

Dependent variables:

- Primary outcome variable – Whether patient spontaneously voided
- Secondary outcome variables:
  - Time that patient spontaneously voided
  - Volume of spontaneous void
  - Whether patient required urinary catheterization or not
  - Patient reported satisfaction with intervention

Potential confounding variables:

- If patient required a second bladder scan, volume of that scan
- Patient's self-reported pain level
- Method of delivery – vaginal or cesarean section
- Whether patient received an epidural or not
- Type of repair
- Whether it was an assisted birth
- Whether patient received duramorph
- Whether patient had foley catheter during stay

- **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 in 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 Intellectus Statistics 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:

  <u>Hypothesis 1</u>: Postpartum patients with urinary retention who are exposed to peppermint oil will experience a higher frequency of resolution of urinary retention compared to postpartum patients with urinary retention not exposed to peppermint oil.

  To compare the effects of the intervention, a Chi Square test will be used to compare occurrence of resolution of urinary retention for patients who received

peppermint oil to patients who did not receive peppermint oil. A level of significance of α=0.05 will be used.

Hypothesis 2: Postpartum patients with urinary retention who are exposed to peppermint oil will experience a shorter time to spontaneous urination compared to postpartum patients with urinary retention not exposed to peppermint oil.

To compare the effects of the intervention, an independent samples t-test will be used to compare mean time to spontaneous urination for patients who received peppermint oil to patients who did not receive peppermint oil. A level of significance of α=0.05 will be used.

Hypothesis 3: Postpartum patients with urinary retention who are exposed to peppermint oil will experience an increased volume of spontaneous urine compared to postpartum patients with urinary retention not exposed to peppermint oil.

To compare the effects of the intervention, an independent samples t-test will be used to compare mean volume of spontaneous urination for patients who received peppermint oil to patients who did not receive peppermint oil. A level of significance of α=0.05 will be used.

Hypothesis 4: Postpartum patients with urinary retention who are exposed to peppermint oil will experience a decreased frequency of urinary catheterization compared to postpartum patients with urinary retention not exposed to peppermint oil.

To compare the effects of the intervention, a Chi Square test will be used to compare occurrence of urinary catheterization for patients who received peppermint oil to patients who did not receive peppermint oil. A level of significance of α=0.05 will be used.

Hypothesis 5: Postpartum patients with urinary retention who are exposed to peppermint oil will experience increased patient satisfaction compared to postpartum patients with urinary retention not exposed to peppermint oil.

To compare the effects of the intervention, a Mann Whitney U test will be used to compare patient satisfaction for patients who received peppermint oil to patients who did not receive peppermint oil. A level of significance of α=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 and HIPAA Authorization Form* and obtain written informed consent. Patients will receive a copy of their signed Informed Consent and HIPAA Authorization form.

  Informed Consent and HIPAA Authorization forms will be stored in a locked area that only study staff will have access to. After the study closes, the signed Informed Consent and HIPAA Authorization 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.

Results (8.12.2025)

Between November 3, 2021 and January 29, 2025, 17 patients were enrolled in the research study.

All patients met the following inclusion criteria:

- 18 years old or older
- English speaking
- Admitted to Bethesda North Mom Baby Unit
- Postpartum
- Experiencing urinary retention – defined as meeting at least one of the following criteria:
  - More than 6 hours after delivery or foley catheter removal without being able to spontaneously void
  - Symptomatic urinary retention without being able to spontaneously void
  - Change in fundal height or position without being able to spontaneously void
- Bladder scan showing bladder containing 400mL or more urine

And patients did not have any of the exclusion criteria:

- Allergy to peppermint
- Asthma
- Active herpes lesions
- Seizure disorder
- Not able to void in toilet (ex: requiring use of bed pan to void)

After consenting to participate in the study, participants were randomized (1:1 randomization) to one of two group:

- Intervention Arm: Subjects will be exposed to vapor of peppermint oil (n=10)
- Placebo Arm: Subjects will be exposed to vapor of placebo/mineral oil (n=7)

	Peppermint Oil n=10	**Placebo n=7**
Scanned Bladder Volume, mL		
Minimum - Maximum	400 – 941	424 – 1000
Mean, SD	648.8, 193	761, 250
Pain Score, 0-10		
Minimum - Maximum	0 – 6	0 – 6.5
Mean, SD	2.1, 2	2.6, 3

Hypothesis 1:

After 10 minutes of sitting on the hat with the oil (peppermint/mineral), 3 of the participants exposed to peppermint oil voided and 1 of the participants exposed to the placebo voided:

	Voided – Yes	**Voided – No**
Peppermint Oil	3	7
Placebo	1	6

A Fisher's Exact Test was performed to determine difference in frequency. A level of significance of 0.05 was used. There is no statistically significant difference in frequency of voiding among women exposed to peppermint oil (30%) compared to women exposed to a placebo oil (14%), p=0.603.

Hypothesis 4:

After 10 minutes of sitting on the hat with the oil (peppermint/mineral), 8 of the participants exposed to peppermint oil required catheterization and all 7 of the participants exposed to the placebo required catheterization:

	Required Catheterization – Yes	**Required Catheterization – No**
Peppermint Oil	8	2
Placebo	7	0

A Fisher's Exact Test was performed to determine difference in frequency. A level of significance of 0.05 was used. There is no statistically significant difference in frequency of requiring catheterization among women exposed to peppermint oil (80%) compared to women exposed to a placebo oil (100%), p=0.485.

Hypothesis 5: *Postpartum patients with urinary retention who are exposed to peppermint oil will experience increased patient satisfaction compared to postpartum patients with urinary retention not exposed to peppermint oil.*

A Mann-Whitney U test was used to determine difference in satisfaction between the two groups. A level of significance of 0.05 was used. There was no statistically significant difference in patient satisfaction between participants exposed to peppermint oil (M=4.4, SD=4) and participants exposed to placebo oil (M=1, SD=0), p=0.116.