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ICE-T Randomized Controlled Trial

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BACKGROUND:

Pelvic floor disorders involve a myriad of complicated, interwoven clinical conditions that involve pelvic organ prolapse, urinary incontinence, fecal incontinence, and other pathology involving the genital and lower urinary tract. It is estimated that pelvic floor disorders affect up to 25% of all adult women in the United States with increasing prevalence with age [1,2] By the age of sixty, 1 in 9 women will undergo surgical intervention for pelvic organ prolapse and/or incontinence, increasing to 1 in 5 by the age of 80.[3] As the population in the United States ages, the demand for healthcare for pelvic floor disorders is estimated to increase up to 40% in the next 30 years. [4,5]

Despite the prevalence of surgery performed for pelvic floor disorders, there is a paucity of data on postoperative pain control that is dedicated to female pelvic reconstructive surgery. In a recent review, there was only one study that evaluated postoperative pain control after vaginal reconstructive surgery, and the mainstay of therapy was opioid driven. [6,7] Generally, postoperative pain control in gynecologic surgery has been opioid driven, frequently involving multiple narcotics for analgesia, resulting opioid related complications, including nausea, vomiting, constipation, urinary retention, and central nervous system side effects. [6]

In an effort to combat opioid use in gynecologic and female pelvic reconstructive surgery, multimodal therapy has been gaining momentum with goals of improved pain control and decreased opioid requirements. [8,9] Ice packs, toradol, and acetaminophen have been used in various trials to decrease postoperative opioid requirements in various surgeries.

Ice packs have been shown to be effective in the treatment of postoperative pain after abdominal midline incisions. [10]A Cochrane Review of patients subject to post vaginal delivery perineal cooling included 10 randomized controlled trials with1825 patients with some evidence that local cooling in the form of ice packs, cold gel packs, cold/ice backs may be effective in pain relief. [11]

Toradol has been extensively studied in a multitude of surgeries including spinal, obstetric, orthopedic, urologic, and gynecologic. It has been administered preemptively, intraoperatively, and postoperatively for pain control with evidence that toradol decreases postoperative subjective pain scores and decreased narcotic use. [12-14]

Acetaminophen is mainstay for postoperative pain control as part of multimodal pain regimens to complement other, opioid sparing medications in a multitude of surgeries including abdominal hysterectomy. [15]

Therefore, the purpose of this randomized controlled study is to determine whether, “ICE-T” a novel multimodal postoperative pain regimen composed of around the clock ice packs, toradol, and tylenol, l has improved pain control and decrease opioid intake compared to the standard postoperative pain regimen in patients undergoing vaginal pelvic floor reconstructive surgery.

HYPOTHESIS: "ICE-T" (around the clock Ice packs, toradol, tylenol) postoperative pain management protocol leads to improved patient perception of pain compared to the standard post operative pain regimen (primary outcome)

QUESTION: Does the ICE-T postoperative pain management protocol lead to improved patient perception of pain compared to the standard post operative pain regimen?

DESIGN: Randomized Control Trial.

SETTINGS: Academic Institution.

EXPERIMENTAL DESIGN AND METHODS:

IRB approval will be obtained at MetroHealth Medical Center and University Hospitals Cleveland Medical Center
This will be a randomized controlled trial that will be conducted at MetroHealth Medical Center and University Hospitals Cleveland Medical Center. Preoperative written consents explicitly explaining the risks and benefits of the study will be obtained from the patients.

The **inclusion** criteria are the following:

-Consenting, English speaking women between ages 18 and 80 who will undergo same day vaginal female pelvic reconstructive surgery at MetroHealth Medical Center and University Hospitals Cleveland Medical Center
-Ability to read VAS Scores

-Specific vaginal procedures include, but are not limited to:

- Periurethral bulking
- Perineoplasty
- Complete vaginectomy
- Le Forte colpocleisis
- Anterior repair
- Posterior repair
- Enterocele repair
- Anterior and posterior repair
- Anterior, posterior and enterocele repair
- Transvaginal mesh use
- Sacrospinous ligament fixation
- Uterosacral ligament suspension
- Vaginal paravaginal defect repair
- Midurethral Sling

- Sphincteroplasty
- Vaginal hysterectomy, for uterus 250 g or less
- Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
- Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele
- Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele
- Vaginal hysterectomy, for uterus greater than 250 g
- Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
- Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele
- Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele

The **exclusion** criteria are the following:

-History of chronic pelvic pain
-History of psychiatric disease
-Currently taking analgesic medications
-Currently taking sedatives
-Liver disease
-Renal disease
-History of burns from application of ice.
-Women who did not consent for the study.
-Intraoperative concern for increased blood loss
-Unable to speak English
-Unable to understand VAS Scores
-Undergoing concomitant abdominal or laparoscopic procedures
-Allergy to motrin, toradol, Percocet, Tylenol.
-Planned abdominal or laparoscopic procedures.

Demographic factors are recorded including, age, BMI, ethnicity, preoperative diagnosis, surgery performed.

Once patients are selected and consents are obtained, they are randomized into the active and control group using computer generated randomization with sequentially numbered opaque sealed envelopes.

Intraoperatively, duration of anesthesia, duration of surgery, estimated blood loss, intraoperative medications are recorded for each type of surgery.

Depending on what postoperative regimen patients will be randomized to they will be given one of the following after surgery:

<u>Regimen #1 “ICE-T” Opioid Sparing Regimen</u>

At the end of surgery patients will receive 30mg of IV toradol.
Once out of the PACU patients will receive
1. ICE PACKS applied to the perineum every two hours for 20 minutes around the clock (ATC) until discharge.
2. 6 hours from the time of first dose of surgery patients will receive 30mg of IV toradol ATC until discharge. The total daily dose of toradol administered is 120mg. Patients will be instructed not to take toradol for more than 5 days total.
3. Once out of the PACU will receive 1 gram of Tylenol every 6 hours for a total of 4 grams daily ATC until discharge
4. Patients will receive dilaudid 0.2mg IV Q3 hr PRN for **breakthrough** pain.
5. Patients will be discharged home with

A. Twenty tablets of Toradol 10mg PO every 6 hours PRN pain. Not to exceed 40 milligrams daily. Patients are informed not take Toradol for more than 5 days total (this included in patient toradol administration.

B. Sixty tablets of Tylenol 1000mg PO every 6 hours PRN pain. Not to exceed 4 grams daily.

C. Patients may continue ice packs at home at their leisure for 20 minutes every 2 hours as needed.

Regimen #2 STANDARD Postoperative Regimen

1. Once out of the PACU patients will receive "Standard" postoperative regimen
2. Motrin 600mg PO Q4h PRN pain 1-3
3. Percocet 1 tab PO Q4-6 hours PRN 4-6 pain
4. Percocet 2 tabs PO Q 4-6 hours PRN 7-10 pain
5. Patients will receive dilaudid 0.2mg IV Q3 hr PRN for **breakthrough** pain.
6. Patients will be discharged home with:

A. 60 tablets of 600mg of motrin PO every 6 hours PRN Pain

B. 20 tablets of Percocet PO every 6 hours PRN Pain.

The medicine will be provided by the nursing staff as per pharmacy orders that patients are randomized to, regimen #1 or regimen #2.

Patients will be provided prescriptions for medications they are discharged home with.

The patients insurance is responsible for the medications.

SAMPLE SIZE:

27 patients in each arm would be needed to achieve 90% power to detect a mean difference of ~25 mm on a 100mm VAS scale for a significance level of 0.05. We will add 20% to account for loss to follow up and we will need **66 patients**, **33 in each arm.** This difference was selected based on multiple previous articles stating that a pain score difference between 20 and 30 is significant for most patients that perceived this as a moderate improvement in their pain after various types of surgery including head and

neck, thoracic, abdominal orthopedic, and spinal. This sample size is in concordance with the sample size of 27 patients in each arm used by Crisp, a urogynecologist, evaluating PCA vs. nurse administered analgesia after vaginal reconstructive surgery patients to determine a significant difference in VAS scores.

30 patients will be recruited at University Hospitals Cleveland Medical Center and a total of 66 patients will be recruited for this study.

OUTCOMES:

PRIMARY OUTCOMES: Visual Analog Scores (VAS) Scores at 7am after surgery

SECONDARY OUTCOMES:
-VAS Scores at PACU exit
-Numerical Pain Scores Scores 96 hours after surgery
-Quality of Recovery scores on post op day 1 (7AM)
-Satisfaction scores in the morning after surgery (7AM)
-Satisfaction scores 96 hours after surgery
-Length of stay
-Hemoglobin difference preop/postop
-Total dose of opioids administered during hospitalization in oral morphine equivalents.
-Postoperative nausea and vomiting with 24 hours of surgery, dizziness, headache, blurry vision, pruritus, drowsiness within 24 hours after surgery,
-Time to first void
-Incidence of urinary retention (discharge home with foley)
-Time to first bowel movement (patients will ask to record this and there will be follow up via phone call 96 hours after surgery).

Statistical analysis will be performed using statistical software, GraphPad. Continuous variables will be analyzed using the t-test/Mann-Whitney test and categorical variables will be analyzed using Chi-Square methods.

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