ELSEVIER

JMIG The Journal of Minimally Invasive Gynecology

Original Article

Surgical Pain Control With Ropivacaine by Atomized Delivery (Spray): A Randomized Controlled Trial

Gretchen G. Collins, MD*, Jill A. Gadzinski, MD, Garrett D. Fitzgerald, MD, Jordan Sheran, MD, Sarah Wagner, MD, Steven Edelstein, MD, and Elizabeth R. Mueller, MD

From the Departments of Obstetrics and Gynecology (Drs. Collins, Gadzinski, Fitzgerald, Sheran, and Wagner), Anesthesia (Dr. Edelstein), and Urology and Obstetrics and Gynecology (Dr. Mueller), Loyola University Chicago Stritch School of Medicine, Maywood, IL.

ABSTRACT **Study Objective:** To investigate the role of intraoperative atomized intraperitoneal ropivacaine (AIR) as an adjuvant to anesthetic agents at the time of minimally invasive pelvic surgery.
Design: Double-blind, randomized controlled trial.
Design: Classification: Randomized controlled trial (Canadian Task Force classification I).
Setting: Tertiary care teaching hospital.
Participants: Fifty-five patients who underwent laparoscopic and robotic gynecologic procedures.
Intervention: Patients received AIR or atomized intraperitoneal saline (AIS) (dose, 2 mg/kg) immediately after the initiation of pneumoperitoneum.
Measurements and Main Results: Visual analog scale (VAS) pain scores and narcotic use (in morphine equivalents) were collected and recorded at 2, 4, 8, and 12 hours postoperatively.
Results: Fifty-five patients completed the study protocol and data collection, with 30 patients allocated to the AIS group and 25 patients allocated to the AIR group. Demographic and surgical variables did not vary between the groups, with the exception of median operative duration. Postoperative VAS scores at 2, 4, 8, and 12 postoperative hours were higher in the AIS group, but the difference failed to reach statistical significance. Narcotic use was also similar in the 2 groups.
Conclusion: The use of intraperitoneal ropivacaine was not associated with a statistically significant difference in patients' postoperative VAS scores. Thus, in contrast to findings of similar studies performed in general surgery, AIR might not confer a benefit in women undergoing minimally invasive gynecologic procedures. Journal of Minimally Invasive Gynecology (2015) ■, ■–■

Keywords: Gynecology; Hysterectomy; Pain; Ropivacaine

DISCUSS You can discuss this article with its authors and with other AAGL members at http://www.AAGL.org/jmig-22-6-JMIG-D-15-00208.

Use your Smartphone to scan this QR code and connect to the discussion forum for this article now*

* Download a free QR Code scanner by searching for "QR scanner" in your smartphone's app store or app marketplace.

In gynecologic surgery, the conversion of open surgical techniques to laparoscopic and robotic-assisted procedures has been associated with decreased pain, bleeding, hospitalization, and faster recovery times [1]. Despite such improvements, however, postoperative pain remains an issue for patients undergoing minimally invasive surgery. Intraperitoneal local anesthesia placement before or after surgery is a novel idea that may help decrease postoperative pain as well as postoperative narcotic consumption [2–4].

Authors from general surgery have reported on the successful use of intraperitoneal local anesthetics. The approaches used have included administering ropivacaine 0.75% or bupivacaine 0.5% at the start of surgery, providing continuous nebulization of 10 mL of 1% ropivacaine, and spraying the diaphragm with 0.5% bupivacaine with

Registered at clinicaltrials.gov (NCT01480089).
Disclosures: None declared.
Portions of this work were presented as an oral presentation at the American Society for Reproductive Medicine's 2014 annual meeting, Honolulu, HI; October 18-22, 2014.
Corresponding Author: Gretchen G. Collins, MD, Department of Obstetrics and Gynecology, Loyola University Chicago Stritch School of Medicine, 2160 S First Ave, Building 103, Room 1004, Maywood, IL 60153.
E-mail: gg.garbe@gmail.com

Submitted April 3, 2015. Accepted for publication July 24, 2015.
Available at www.sciencedirect.com and www.jmig.org

1553-4650/$ - see front matter © 2015 AAGL. All rights reserved.
http://dx.doi.org/10.1016/j.jmig.2015.07.018

epinephrine before and after surgery [2–4]. A recent study by Kang and Kim [5] demonstrated a significant reduction in postoperative visual analog scale (VAS) pain scores in patients who received atomized intraperitoneal ropivacaine (AIR) before laparoscopic appendectomy. Boddy et al [6] performed a systematic review and meta-analysis of 24 randomized controlled trials using intraperitoneal local anesthesia in laparoscopic cholecystectomy and concluded that the use of intraperitoneal local anesthesia is safe and results in a statistically significant reduction of early postoperative pain.

Given that intraperitoneal administration of local anesthetic agents has been shown to be beneficial and safe for patients undergoing laparoscopic abdominal surgery, we hypothesized that women undergoing minimally invasive pelvic surgery would see similar reductions in postoperative pain. The aim of the present study was to investigate the role of intraoperative AIR as an adjuvant to anesthetic agents at the time of minimally invasive gynecologic surgery.

Materials and Methods

We recruited 55 women undergoing minimally invasive laparoscopic surgery from the urogynecology, benign gynecology, and gynecologic-oncology clinics for this Institutional Review Board (IRB)-approved study (Loyola IRB no. 203353021611). All women who were scheduled to undergo a minimally invasive hysterectomy for benign and cancerous conditions between February 2012 and March 2013 were invited to participate. Subjects who met the following inclusion criteria were considered eligible: age 18 to 75 years, ability to independently complete the study documents, and willingness to complete these study documents while in the hospital postoperatively. Informed consent was obtained from each patient entered in the study. Exclusion criteria included pregnancy, allergy to local anesthetic agents, and severe underlying cardiovascular, renal, or hepatic disease.

To calculate the sample size needed for this study, we used data from a similar study performed by Kang and Kim [5] in patients undergoing laparoscopic appendectomy. We assumed that the pain associated with laparoscopic surgery and robotic-assisted laparoscopic pelvic surgery are similar. Before study initiation, the 2-hour postoperative VAS pain scores of patients who underwent robotic sacrocolpopexy at Loyola University Medical Center were reviewed to ensure that the study populations had similar baseline pain levels as the controls in the Kang and Kim study (34 mm). We found a 2-hour VAS scores for patients undergoing robotic sacrocolpopexy of 35 mm, the same baseline VAS score as that of the patients in the Kang and Kim study. A 2-tailed error of 5% and a β error of 10% were accepted to detect differences in pain scores of 20 mm between the 2 groups (AIR vs AIS). Based on these calculations, the required sample size was 25 patients per group.

We calculated that 20% of patients would not be randomized owing to failure to schedule surgery, and thus we planned to enroll 30 patients in each group. However, we decided a priori to stop the study once 25 patients were randomized to each group. Because we did not randomize in a block format, we enrolled 30 patients in the AIS arm before we had randomized 25 patients to AIR. This is an "intention-to-treat" study, and as such we decided a priori that if patients received the study medication and then were converted to an open procedure, their postoperative VAS scores would be included in the analysis.

Randomization into the AIR or AIS group was based on Excel (Microsoft, Redmond, WA) random number generation and stratified based on the route of surgery (pure laparoscopic vs robotic-assisted laparoscopic). The details of the series were unknown to the investigators (surgeons and anesthesia teams) and patients. Sequentially numbered, opaque, sealed envelopes were kept in the operating room pharmacy. Once the patient was in the operating room but before anesthesia induction, the appropriate numbered sealed envelope was opened by the operating room pharmacist and the study drug (ropivacaine, dose of 2 mg/kg lean body mass, or saline) for that case was sent to the operating room in a sealed package with the case number and the label "study drug." A patient with a calculated lean body mass of >100 kg received only 200 mg of ropivacaine or its saline equivalent. At no time did any patient receive a dose >200 mg. The volume of the study drug was made the same for each patient by diluting the study drug to a final volume of ~100 mL.

Following a standardized protocol for the induction and maintenance of anesthesia, the surgical procedure was initiated as usual. The patient was positioned, prepped, and draped. The laparoscopic or robotic ports were inserted after injection of Marcaine at the port site, starting with the camera port and 2 assistant ports. The drug was administered through an Optispray atomization device (Wolfe-Tory Medical, Salt Lake City, UT), a sterile, one-time-use instrument specially designed to administer topical anesthetic in the manner described in this protocol. The device consists of a 35-cm stiff, malleable tubing with a Luer-lock fitting for a syringe at the proximal end and an atomizer nozzle at the distal end. The syringe containing the study drug is attached to the Luer-lock fitting after all air bubbles are removed. The syringe plunger is engaged, and the syringe fluid is pushed through the atomizer nozzle, resulting in a fine aerosolized spray that can be easily directed by bending the malleable tubing. used a laparoscopic camera for visualization, the surgeon delivered the study drug in the following manner. The first 50% of the drug (~50 mL) was sprayed on the anterior abdominal wall starting at the umbilicus up to and including the diaphragm. Then a second syringe of 25% of the study drug (~25 mL) was sprayed on the anterior abdominal wall from the umbilicus to the anterior bladder wall. Finally, the remaining 25% of the drug (~25 mL) was sprayed into the pelvis, starting at one pelvic side wall and spraying everything below the umbilicus to the opposite side wall.

The surgeon, anesthesiologist, and rest of the surgical and anesthesia team were blinded to the contents of the "study solution" (ropivacaine or saline). The patient was left in the supine position for 5 minutes as additional ports were placed. After 5 minutes, the patient was positioned based on standard operating practice of the surgeon. The remainder of the surgery progressed as usual.

The preoperative and intraoperative anesthesia protocol did not deviate from the standard induction and intraoperative anesthesia protocol, and the exact medications and doses were recorded on the anesthesia intake form. All patients received the same postoperative pain control. All patients who did not have an allergy or contraindication to Toradol were given scheduled, age-adjusted doses every 6 hours, along with a narcotic pain medication in accordance with the standard of care at our institution. Depending on the type of surgery, patients received either synthetic narcotic (Norco) or morphine patient-controlled analgesia. Patients allergic to morphine were given a narcotic substitute, which was converted to morphine equivalents for the purpose of the study. All patients who reported nausea received given intravenous Zofran 4 mg every