ELSEVIER

THE JOURNAL OF
MINIMALLY INVASIVE
GYNECOLOGY

Original Article

A Comparative, Single-Blind, Randomized Trial of Pain Associated with Suction or Non-Suction Drains after Gynecologic Laparoscopy

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ABSTRACT **Study Objective:** To estimate the difference in pain associated with the wearing or removal of suction or non-suction drains after gynecologic laparoscopic surgery.

Design: A randomized controlled trial from August 2006 through October 2007 (Canadian Task Force Classification I).

Setting: Royal Hospital for Women, Department of Endo-Gynaecology and School of Women's and Children's Health University of New South Wales.

Patients: A total of 168 women undergoing gynecologic laparoscopy requiring postoperative drainage.

Interventions: Patients were randomized to receive either a suction or non-suction drain after surgery.

Measurements and Main Results: Pain was assessed before, during, and after drain removal with a 4-point verbal descriptor scale and 10-cm visual analogue scale. Visual analogue scale and verbal descriptor scale scores for suction versus non-suction groups were 3 versus 3 ($p = .654$) and 1 versus 1 ($p = .686$) before removal, 9 versus 7 ($p = .016$) and 3 versus 2 ($p = .029$) during removal, and 7 versus 5 ($p = .058$) and 2 versus 2 ($p = .122$) after removal.

Conclusion: There is no significant difference in patient discomfort while wearing or after removal of suction or non-suction drains. However, suction drains are more painful to have removed. Journal of Minimally Invasive Gynecology (2010) 17, 16–20 © 2010 AAGL. All rights reserved.

Key Words: Drainage; Gynecologic laparoscopy; Non-suction drain; Pain; Suction drain

The presence of gas or fluid in the peritoneal cavity after laparoscopic surgery may increase a patient's risk of pain, infection, or other complications [1-5]. To reduce this risk, drains are often placed at the end of surgery, although the choice of drain is discretionary. There are a number of closed drainage systems that may be used either with or without suction. Previous work from our unit has demonstrated that these 2 types of drains are equally effective at removing fluid from the pelvis [6].

Numerous studies suggest that drain placement after laparoscopy may play a role in reducing patients' pain after surgery [1-3]; however, it is unclear whether these benefits are more strongly associated with a particular type of drain. Conversely, drains may be a source of discomfort because of direct irritation, tissue erosion, obstruction, or entanglement [7]. This randomized study aims to compare suction and non-suction drains with regard to the comfort of wearing and removal.

Material and Methods

This study was approved by the South Eastern Sydney Area Health Service Scientific Committee and Human Research Ethics Committee (ref 06/150 granted August 29, 2006) and undertaken at the Department of Endo-Gynaecology, Royal Hospital for Women, Randwick, Australia. This trial was registered with the Australian and New Zealand Clinical Trials Registry (www.anzctr.org.au), ACTRN 12608000109303. From August 2006 through October 2007, women undergoing elective surgery in our unit were invited to participate in the study.

The authors have no commercial, proprietary, or financial interest in the products or companies described in this article.

Presented at the 37th Meeting of the AAGL, October 28–November 1, 2008 Las Vegas Nevada.

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Submitted February 4, 2009. Accepted for publication April 16, 2009.
Available at www.sciencedirect.com and www.jmig.org

1553-4650/$ - see front matter © 2010 AAGL. All rights reserved.
doi:10.1016/j.jmig.2009.04.010

Eligible women were aged 18 to 80 years, fluent in written and spoken English, able to provide informed consent, and scheduled to undergo major gynecologic laparoscopic surgery with the possibility of requiring placement of a drain at the discretion of the surgeon. Suitable procedures included resection of endometriosis, hysterectomy, myomectomy, salpingectomy, oophorectomy, ovarian cystectomy, urethropexy, or any combination thereof. Patients were excluded if they had a known or suspected pregnancy, a gynecologic malignancy or premalignant condition, or any other intercurrent condition that, in the investigator's opinion precluded a patient from participating in the study.

Patient information statements were provided before surgery and informed consent sought and signed before inclusion in the study. Patient demographics were collected on the day of surgery. Demographic data included age, body mass index, ethnicity, smoking status, type (if any) of previous abdominal surgery, number of prior laparoscopies or laparotomies, and primary indication for surgery.

Desired sample size was calculated on the basis of finding a clinically significant reduction in pain, estimated to be 20%, between the 2 groups. Given a power of 80% and with significance set at the 0.05 level, this was determined to be 160, with 80 subjects in each arm using a 1:1 ratio for the groups. Allowing for a 10% loss for incomplete data sets and protocol violations, we sought to recruit 180 patients in total.

Randomization was by computer-generated randomization sequences in balanced blocks of 20. Patients were randomly assigned to have their drain placed on suction or to have no suction applied to the drain. Randomization occurred at the completion of the subjects' surgery, once the surgeon deemed drain placement appropriate. If a drain was not required, the patient was removed from the trial. Concealment was achieved by placing the allocations into consecutively numbered opaque envelopes. These were stored in the operating theater and opened after the decision to place the drain was made.

For patients randomized to the study, a Bellovac Set FG 14 (Astra Tech, Mölndal, Sweden) drain was placed through the left lateral port site. The vacuum pack was compressed if the patient was randomized to the suction group or left open if the patient was randomized to the non-suction group. To aid blinding, the vacuum pack was positioned below the bedside, out of the patients' sight. Postoperative analgesia was administered as per the instructions of the anesthetic and surgical staff. The drain was removed when it was considered medically indicated, that is when the volume of fluid in the drain was less than 50 mL in an 8-hour nursing shift or if the fluid being removed was serous. At no time were patients' requests for additional pain relief denied.

Pain was assessed with 2 instruments, a 4-point verbal descriptor scale (VDS) and a 10-cm visual analogue scale (VAS). For the VDS, patients were asked to select the category best describing their current level of pain: 0 = no pain, 1 = mild pain, 2 = moderate pain, or 3 = severe pain. For the VAS subjects were asked to place a cross anywhere along a 10-cm line, the left side of which was marked ''no pain'' and the right marked ''worst imaginable pain.'' A score was obtained by measuring the distance left to right where the cross or line transected the baseline. The presence of nausea or vomiting was categorically recorded. Initially, these assessments were performed twice: 5 minutes before and 5 minutes after drain removal. After a review of the method was performed in March 2007, it was believed that additional data might be gained by a third assessment, with the VDS and VAS used during removal of the drain (the VAS was completed as the drain was completely removed from the abdomen; the VDS during drain removal). This protocol change was approved by the Ethics Committee and implemented from May 2007.

The amount of analgesia consumed by each subject was also documented. This was recorded as total opioid dose, total nonsteroidal antiinflammatory drugs (NSAIDs), and total acetaminophen consumed before and after drain removal. For the purposes of data comparison, opioids were converted to a 10-mg morphine equivalent. Any dose of an opioid unable to be accurately described in terms of morphine equivalency or unable to have its administered dosage reasonably measured was assumed to be equivalent to 10 mg of parenteral morphine. NSAID and acetaminophen consumption was compared by dose.

Intergroup analysis for independent parametric data was assessed using the Student t test, or the Mann Whitney U test for its nonparametric equivalent. Dichotomous data were compared by use of χ^2 and Fischer's exact test as appropriate to sample size. Statistical analyses were performed with SPSS 14.0 (SPSS, Inc., Chicago, IL).

Results

During the study period, 263 eligible women were approached for inclusion in the study and 168 women were randomized to a study group. One hundred sixty-one complete data sets were collected, 82 in group 1 (non-suction) and 79 in group 2 (suction). The additional assessments during drain removal were completed in 66 subjects, 36 in group 1 and 30 in group 2. Fig. 1 demonstrates patient disposition through the study. Comparisons of demographic and surgical factors demonstrate no significant difference between groups (Table 1). There was no difference between groups for primary indication of their index surgery ($\chi^2 = 1.829$, $p = .767$).

No significant difference in pain scores was found between groups either before or after drain removal (Table 2). Pain scores taken during removal demonstrated a statistically significant difference, with suction drains being more painful (Table 2). There was no significant difference in the incidence of nausea and vomiting (Table 3), or total analgesic consumption (Table 4) between groups. Ninety-eight subjects were administered analgesia expressly for the purpose of drain removal, 48 (58.5%) allocated to non-suction and