

# Improved Post-Operative Analgesia with Intraperitoneal Lidocaine Installation in Abdominal

## Surgery; A Randomized, Double-Blind, Placebo-Controlled Trial.

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### Background

In 2017, narcotic overdose related deaths in the United States peaked at just over 70,000.<sup>1,2</sup> Of the ten Million Americans that misused opioids in 2018, over 90% misused prescription pain medications.<sup>3</sup> New persistent opioid use after surgical procedures occurs at a rate of 5.9 – 6.5%.<sup>4</sup> In short, the routine use of narcotic analgesics during surgery significantly contributes to the ongoing narcotic crisis in America. At SBH Multimodal analgesia was introduced into perioperative medicine in 2018. A review of the perioperative Surgical Information Systems –database establishes that by January 2019 the use of narcotic analgesics in the perioperative phase of care had decreased by 30%. While this same database demonstrates decreasing post-operative pain scores and shorter Post Anesthesia Care Unit length of stay in general, there remains a population of patients in which postoperative pain management may still be insufficient. This population is at increased risk of developing severe post-operative pain and the conversion from acute to chronic post-operative pain. The incidence of chronic postoperative pain varies with the type of operation and the efficacy of acute pain control and has been reported to be as high as 1:2.5.<sup>5</sup> Chronic post-operative pain can induce significant stress, impair function, increase prolonged narcotic use which remains an important issue.

Multimodal analgesia is a method of pain management that provides synergistic analgesia by combining various groups of medications and routes of delivery to achieve the relief of pain, while maintaining a better overall side effect profile than increasing doses of any single agent. Local anesthetics are among the most used agents in a multimodal pain management plan. In addition to topical application and local infiltration, Local anesthetics have been safely used to provide perioperative analgesia when given through the intravenous, epidural, intrathecal, and intraperitoneal routes.

Intraperitoneal instillation of local anesthetic (IPLA) known to provide effective analgesia and has been used extensively in laparoscopic abdominal and gynecological surgery. Perhaps the main advantages of IPLA is that there is little addictive potential and they are not associated with the adverse effect profile of systemically administered opioids.<sup>6</sup>

### Objectives

Intraperitoneal instillation of local anesthetic has been used extensively in laparoscopic surgery and is well recognized for its safety profile, ease of use and efficacy as a single modality for the mitigation of postoperative pain.<sup>7-11</sup> Previously, IPLA has been shown to be effective in the post-operative pain management of patients undergoing open surgical hysterectomy and most recently as an adjunct in post-operative multimodal analgesia for patients undergoing open surgical Cesarean Delivery.<sup>6,12</sup> The success of IPLA as a cross over from lower abdominal laparoscopic to lower abdominal open surgery suggests that similar success should follow when this modality is added to a Multimodal regimen for upper abdominal surgery as well. Currently, the most common multimodal approach to pain management for upper abdominal surgery includes: Regional anesthesia, Gabapentin as a premed, Intraoperative Tylenol, Steroid and non-steroid anti-inflammatory agents (NSAIDS) with PCA for post-operative analgesia. A transverse Abdominal Plane block (TAP block) is also commonly added for open abdominal surgery. In this study we will investigate the success of intraperitoneal instillation of the local anesthetic lidocaine as an adjunct to the current multimodal analgesia regimen used in abdominal surgery.

### Methods

This was a two-arm study

ARM one 40 patients scheduled for open abdominal surgery

- Standardized general endotracheal anesthetic. Including: Propofol, Midazolam and Rocuronium. Sevoflurane, Oxygen and Nitrous oxide.

- No narcotic analgesics were scheduled to be given. All patients received Multimodal analgesia (MMA)

- Prior to the induction of anesthesia patients were randomized:

- Group A: 20 ML of local anesthetic (Lidocaine 2% total 400 mg with epinephrine 1:200,000.(total 100mcg)

- Group B: 20 ml of sterile normal saline

- Prior to closing the peritoneal cavity the designated solution would be decanted in sterile fashion into a basin on the sterile field and gently instilled into the peritoneal cavity, in no specific format or direction, by the surgeon.

- The surgical team and the patient remained blinded to which solutions was used.

- The Anesthesiology provider remained unblinded so that any perceived complication could be managed with appropriate therapy without delay.

- All patient' with open abdominal surgery had MMA. with the addition of a TAP block tap block

- At the PACU all patients received instructions and were provided with a PCA device

- PACU Nurses remained blind to which solution the patient received.

- All patients were monitored for 60 min for evidence of local anesthetic absorption and toxicity and met standard Aldrete criteria prior to discharge.

Arm two: 40 patients scheduled for laparoscopic surgery

- Standardized general endotracheal anesthetic. Including: Propofol, Midazolam and Rocuronium. Sevoflurane, Oxygen and Nitrous oxide.

- No narcotic analgesics were scheduled to be given. All patients received Multimodal analgesia (MMA)

- Prior to the induction of anesthesia patients were randomized:

- Group A: 20 ML of local anesthetic (Lidocaine 2% total 400 mg with epinephrine 1:200,000.(total 100mcg)

- Group B: 20 ml of sterile normal saline

- Prior to removing the final laparoscopic trocar the designated solution would be decanted in sterile fashion into a basin on the sterile field and gently instilled into the peritoneal cavity, in no specific format or direction, by the surgeon.

- The surgical team and the patient remained blinded to which solutions was used.

- The Anesthesiology provider remained unblinded so that any perceived complication could be managed with appropriate therapy without delay.

- \*No TAP block was administered for patients undergoing laparoscopic surgery

- At the PACU all patients received instructions and were provided with a PCA device

- PACU Nurses remained blind to which solution the patient received.

- All patients were monitored for 60 min for evidence of local anesthetic absorption and toxicity and met standard Aldrete criteria prior to discharge.

### Results

All patients were assessed hourly for the first 5 hours after surgery.

Pain was assessed on a 10-point visual analog scale.

Patient satisfaction was assessed on a 5-point Likert scale

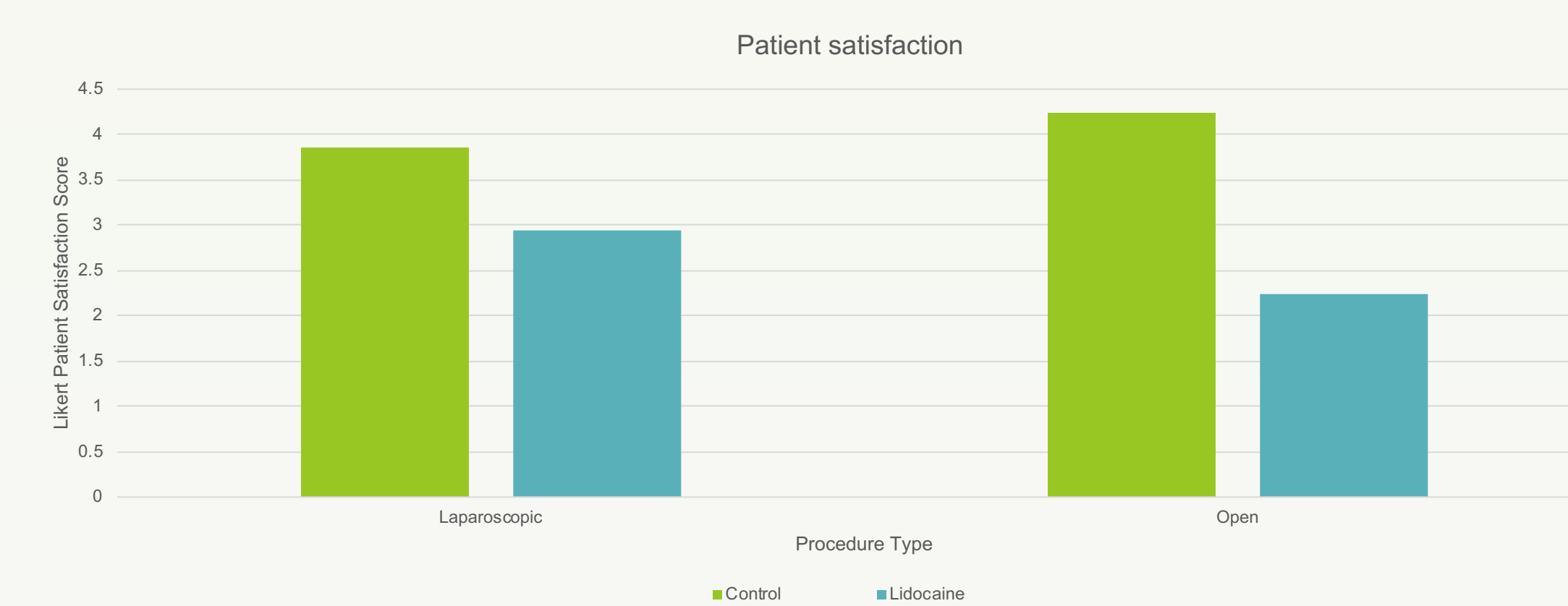
Pain scores favored MMA + IPLA over MMA in both groups.

Patient satisfaction favored the MMA with out IPLA group in the open and laparoscopic groups

- The laparoscopic group favored MMA+IPLA over MMA**
  - at one hour the MMA+IPLA group reported almost 50% less pain than the MMA without IPLA group
  - The difference in pain scores between those receiving MMA+IPLA for laparoscopic surgery and those that received only MMA decreased over time but still favored IPLA
- The group that had open surgery favored MMA+ IPLA over MMA**
  - At one hour the difference in reported pain scores was small
  - Over time the difference in reported pain scores diverged strongly favoring MMA+IPLA.

\*Statistical significance could not be calculated due to small sample size.

Laparoscopic arm N=35 Open abdominal surgery N=8



Patients' satisfaction with post operative pain control between MMA and MMA plus IPLA, laparoscopic and open abdominal surgeries. Pt. satisfaction was recorded on 5-point Likert scale (1= extremely dissatisfied, 2= somewhat dissatisfied, 3= neutral, 4= somewhat satisfied, 5= extremely satisfied). Values are the average satisfaction score for that category.

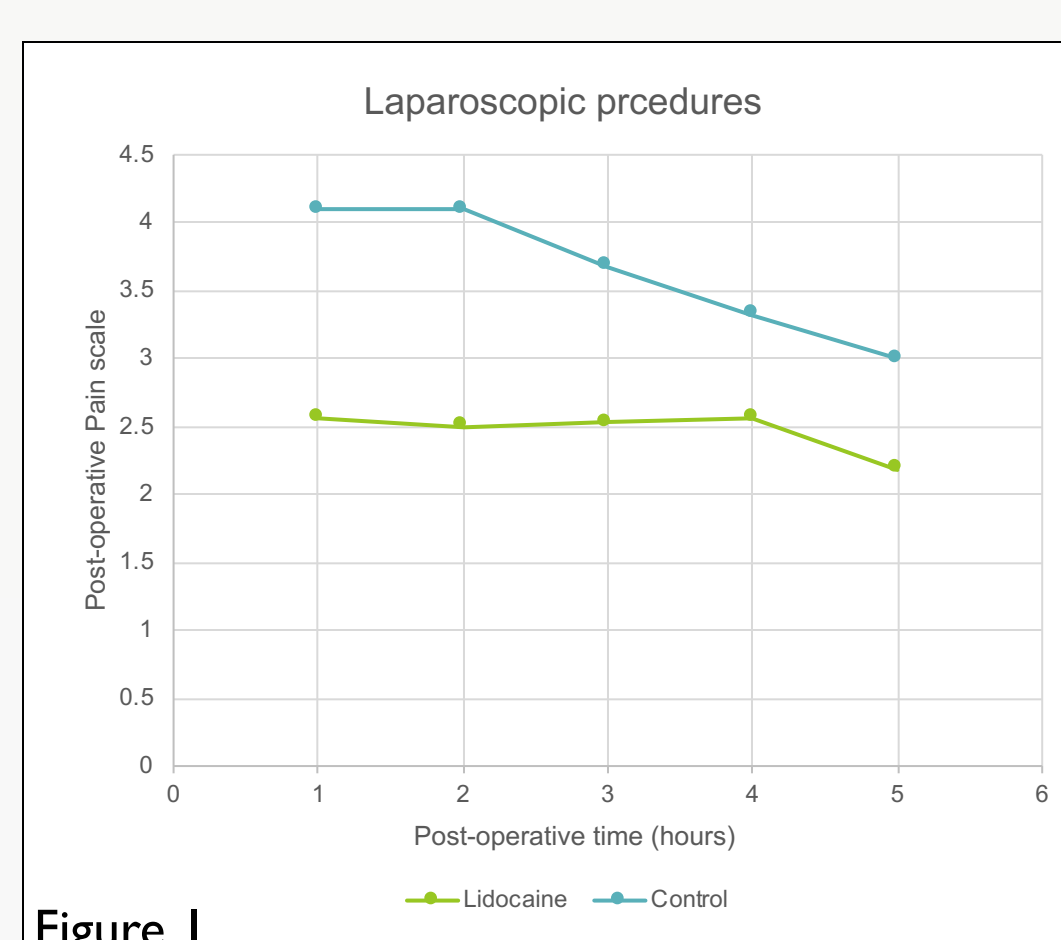


Figure 1.

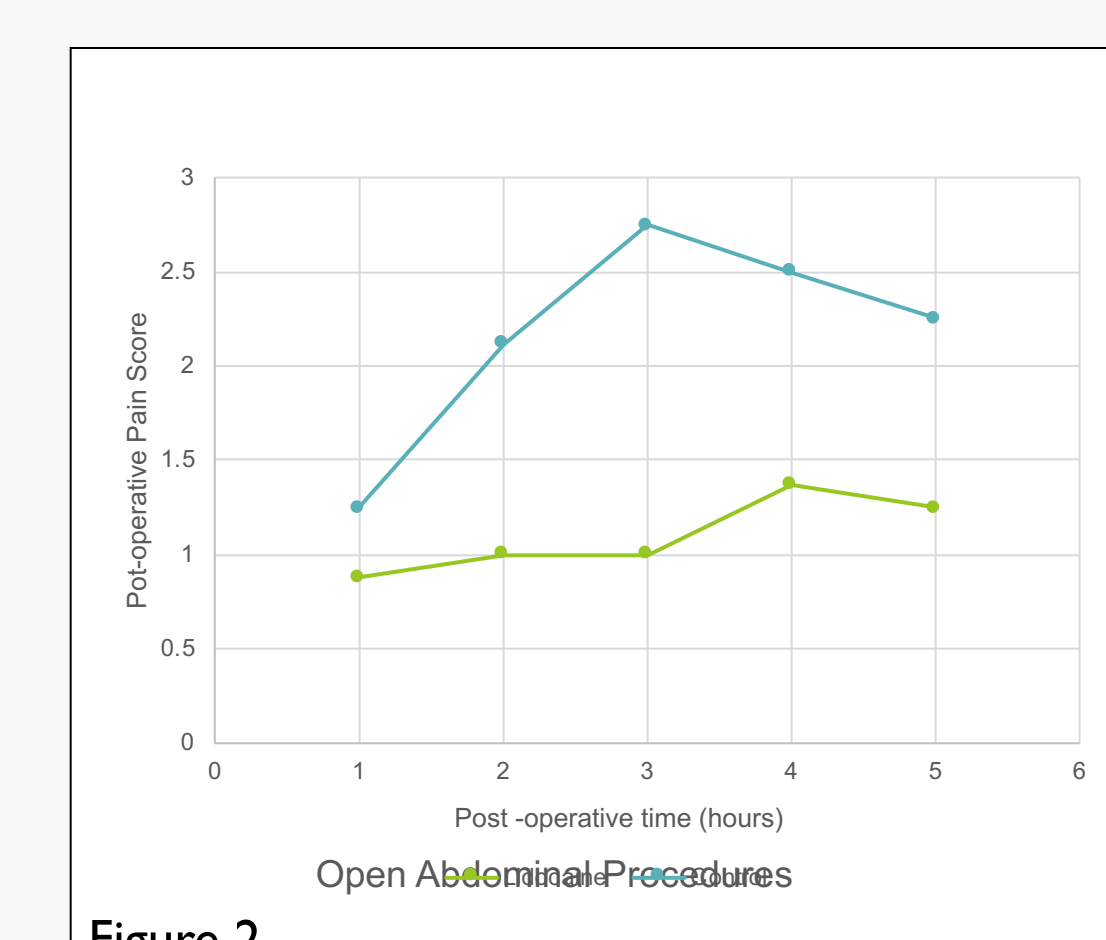


Figure 2.

Diagrams show the comparison between MMA, and MMA with intraperitoneal lidocaine. Fig 1. laparoscopic Fig 2. Open abdominal surgeries.

### Discussion

Due to the relatively low volume of open surgery and the pandemic induced interruption of non emergent surgery an insufficient number of subjects were enrolled in this study to make any valid analysis. The value of this study as a pilot is a strong suggestion that the study and its findings will be significant if it is appropriately powered.

As a pilot this study gives us a good idea of the incident rate of significant post operative pain in both the laparoscopic and open abdominal surgical populations and a better estimate for the number necessary to treat to validate IPLA as a usable modality to enhance post operative MMA.

Despite the inadequate sample size the early trends do suggest that IPLA may have a role in the Multimodal treatment of post operative pain for patients having open and laparoscopic surgery.

While there is some debate in the literature about the validity of the TAP block the relatively low immediate pain scores after open abdominal surgery where the patient did receive a tap block suggests some value. In order to validate this finding the study should continue to its natural end point where statistical significance can be attained.

This study did attempt to calibrate PCA utilization as a marker for adequate pain control however the use of PCA was negligible indicating that the MMA may be sufficient to adequately control post operative pain in both the laparoscopic and open surgery group with out the need to implement narcotic therapy as a routine. Larger studies will validate this point as well

### Conclusion

Although too small to reach clinical significance, the preliminary results of this study favor adding IPLA to the MMA protocol for both open and laparoscopic abdominal surgery. Further testing is in order to validate this early data to its natural conclusion. The lack of PCA use suggests an additional opportunity to decrease the automatic use of narcotic in post operative surgical patients and an opportunity to flatten the curve of the narcotic crisis.

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