

Treatment with Lavender Aromatherapy in the Post-Anesthesia Care Unit reduces Opioid Requirements of Morbidly Obese Patients Undergoing Laparoscopic Adjustable Gastric Banding

Jung T. Kim, MD¹; Christine J. Ren, MD²; George A. Fielding, MD²; Abhishek Pitti, MD¹; Takeo Kasumi, MD¹; Michael Wajda, MD¹; Allen Lebovits, PhD¹; Alex Bekker, MD, PhD¹

¹Departments of Anesthesiology and ²Surgery, New York University Medical Center, New York, NY, USA

Background. Parenteral administration of opioids and NSAIDs has been the mainstay for postoperative pain control in patients undergoing laparoscopic adjustable gastric banding (LAGB). Both classes of drugs, however, are associated with serious adverse effects. An addition of complimentary analgesic techniques may decrease requirement for traditional analgesics, thus reducing the incidence of side-effects. We designed the study to evaluate the effectiveness of Lavender aromatherapy in reducing opioid requirements after LAGB.

Methods: A prospective randomized placebo controlled study was carried out on 54 patients undergoing LAGB. Upon arrival to the post-anesthesia care unit (PACU), patients in the study group were treated with lavender oil, which was applied to the oxygen face mask; the control group patients received non-scented baby oil. Postoperative pain was treated with morphine. Numerical rating scores (0-10) were used to measure the level of pain at 5, 30, and 60 min. Sedation was evaluated using the Observer Assessment of Alertness/Sedation scale (0-5). Data analyzed included the amount of opioids, NRS, OAA/S, PACU discharge time, as well as the incidence of side-effects.

Results: The two groups were comparable with regard to patient characteristics, intraoperative drug use, and surgical time. Significantly more patients in the Placebo group (PL) required analgesics for postoperative pain (22/27, 82%) than patients in the

Lavender group (LAV) (12/26, 46%) ($P=.007$). Moreover, the LAV patients required significantly less morphine postoperatively than PL patients: 2.38 mg vs 4.26 mg, respectively ($P=.04$). There were no differences in the requirements for postoperative antiemetics, antihypertensives, or PACU discharge time.

Conclusions: Our results suggest that lavender aromatherapy can be used to reduce the demand for opioids in the immediate postoperative period. Further studies are required to assess the effect of this therapy on clinically meaningful outcomes, such as the incidence of respiratory complications, delayed gastric emptying, length of hospital stay, or whether this therapy is applicable to other operations.

Key words: Morbid obesity, laparoscopic surgery, bariatric surgery, postoperative pain, gastric banding, lavender oil, aromatherapy, opioid

Introduction

Laparoscopic adjustable gastric banding (LAGB) is a fast-emerging surgical therapy for severely obese patients. Compared to open gastric bypass, LAGB offers a lower incidence of perioperative complications as well as shorter hospital stay.¹ Although LAGB results in less postoperative pain than open procedures, it is not pain free. Inadequate pain control may negate the purported advantages of LAGB, such as lower incidence of pulmonary complications, stable hemodynamics, and early mobilization.

Correspondence to: Alex Bekker, MD, PhD, Associate Professor of Anesthesiology and Neurosurgery, Director of Clinical Research, Department of Anesthesiology, New York University Medical Center, 560 First Ave, New York, NY, 10016, USA. E-mail: alex.bekker@med.nyu.edu

Perioperative analgesia has traditionally been provided by opioid analgesics. It has been well documented, however, that opioid analgesics increase incidence and severity of respiratory depression, nausea/vomiting, pruritis, urinary hesitancy, and ileus.² The currently advocated strategy for postoperative analgesia includes the use of more than one class of medications to produce analgesia through multiple mechanisms (multimodal analgesia).³ Non-steroidal antiinflammatory drugs (NSAIDs), such as ketorolac, are frequently added for postoperative pain control in patients without history of gastroesophageal reflux. The use of NSAIDs, however, may be associated with GI bleeding, blood dyscrasias, and, in rare cases, renal failure.⁴ An addition of non-opioid, non-NSAID therapies might reduce requirements for both classes of medication, thus reducing the associated adverse effects.

The use of complimentary non-pharmacological adjuvant therapies are advocated as a part of a multimodal approach to reducing pain, anxiety, and emetic symptoms in the perioperative period.⁵ The Acute Pain Management Guideline Panel specifically states that nonpharmacological therapies should be considered for any patient with an interest or acceptance of these techniques as a component of a multimodal pain management strategy.⁶ Aromatherapy is one of the potential methods of reducing postoperative pain and improving patients' satisfaction. Lavender oil aromatherapy, in particular, has been credited with mood-enhancing and analgesic properties by aromatherapists.⁷ Our recent study demonstrated that patients treated with lavender oil reported a higher satisfaction rate with pain control than placebo group in patients undergoing breast biopsy.⁸ The current study was designed to test whether aromatherapy with lavender oil would improve the postoperative course of patients undergoing an intra-abdominal procedure, specifically gastric banding surgery. To test this hypothesis, we conducted a prospective, randomized, placebo-controlled study. Our primary outcome criterion was the proportion of patients who required analgesics in the immediate postoperative period. In addition, we investigated whether there was any effect of lavender oil on pain level, narcotic use, and length of stay in the Post-anesthesia Care Unit (PACU).

Materials and Methods

Subjects

This study was approved by the Institutional Review Board (IRB) of New York University School of Medicine. Fifty-four patients with ages between 18 and 65 years and with American Society of Anesthesiologists (ASA) physical status of I-III scheduled for LAGB surgery were recruited to participate in the study. Patients with a history of asthma, bronchitis, chronic obstructive pulmonary disease, contact dermatitis to cosmetic fragrances, or who were pregnant at the time of surgery were excluded.

Study Design

Patients who consented to the study were randomized into two groups, according to a predetermined random sequence. They were treated with a lavender oil patch test to rule out sensitivity to lavender preoperatively. Two drops of lavender oil were applied to the inside of a patient's wrist. Upon arrival to the PACU after surgery was completed, the patients in the lavender group (LAV) received oxygen with a face-mask coated with lavender oil. Two drops of 2% lavender oil were applied with a cotton swab to the inside of an oxygen facemask. Patients in the placebo group (PL) received oxygen coated with non-scented baby oil upon arrival to the PACU.

Anesthetic Management

All patients were monitored according to ASA standard practice guidelines. Prior to induction, all patients received midazolam 2 mg, metoclopramide 10 mg, and ondansetron 4 mg IV. Anesthesia was induced with fentanyl 1.5 µg/kg and propofol 2-2.5 mg/kg. Sevoflurane was used for the maintenance of anesthesia. The patients received ketorolac 60 mg intramuscularly at the end of the procedure if not contraindicated. Subcutaneous injections of morphine were used for postoperative pain control. Labetalol (or hydralazine), trimethobenzamine, and famotidine were used in the PACU to control hypertension, nausea, and dyspepsia respectively.

Data Collection

Pain intensity was evaluated with a numeric rating

scale (NRS: 0 = no pain to 10 = severe pain). Patients were treated with morphine, 2 mg SC, if NRS score was >2. The five-points Observer's Assessment of Alertness/Sedation scale (OAA/S) was used for assessing the patients' sedation level in the PACU (1 = no response to mild prodding or shaking; 2 = responds only after mild prodding; 3 = responds to name only if called repeatedly, slurring speech; 4 = lethargic response to name, mild slowing of speech; 5 = responds readily to name, normal speech). Additional in-hospital evaluations included total amount of opioids, as well as other medications (antihypertensives and antiemetics). We also documented discharge time from the PACU. Patients were assessed at 5, 30, and 60 minutes from PACU arrival. Any adverse effects of lavender aromatherapy were documented. Discharge criteria included preoperative level of consciousness, stable vital signs, and respiratory stability.

Statistical Methods

Two-factor (group and time) analyses of variance with repeated measures were performed on the continuous outcome variables (postoperative pain scores and sedation scores) comparing differences between the lavender and placebo groups. Main effects were evaluated for differences between the study and comparison groups, as well as effects over time, and interaction effects (differences between groups over time). Categorical variables (percentage of patients who had received a postoperative pain medication,

gender differences) were evaluated for between group differences with non-parametric statistics such as chi-squares. Independent *t*-tests were performed on the demographic variables (age, weight, height, BMI) as well as on pain and sedation scores at each assessment point, to further evaluate the efficacy of the intervention. Analyses were performed using SPSS (version 10.0).

Results

We randomized 54 patients. One patient from the LAV group was excluded from analysis due to protocol violation (patient was taken to the PACU intubated). Demographic characteristics, duration of surgery, PACU time, and baseline pain intensity were similar in both groups (Table 1). However, the LAV patients weighed less than placebo (126.7 kg vs 112.9 kg, $t=2.60$, $P=.012$) and had a lower BMI (44.0 kg/m² vs 40.2 kg/m², $t=2.19$, $P=0.034$). Four patients in the LAV and two patients in the PL had severe gastroesophageal reflux and were not treated with ketorolac.

Pain intensity levels were similar in both groups during the duration of the study. ANOVA with repeated measure for pain scores showed a significant time effect but no significant group effect. Pain decreased over time, but not differently between groups (time $F=16.85$, $P<.0001$, Group $F=.37$, $P<.55$). Similarly, sedation scores increased with time, but there were no differences between groups.

Table 1. Demographic and Perioperative Characteristics of the Treatment Groups

	Placebo Group N = 27	Lavender Group N = 26
Age (yr)	43.3 ± 12.5	45.9 ± 12.0
Gender (M/F)	11/16	9/17
Weight (kg)	126.7 ± 16.9	112.9 ± 19.8 *
BMI (kg/m ²)	44.0 ± 6.1	40.2 ± 5.8 *
Pain Score on arrival to PACU (0-10)	2.7 ± 2.8	4.1 ± 2.4
Pain score at Discharge from PACU (NRS: 0-10)	2.2 ± 1.8	2.3 ± 1.3
Sedation score on arrival to PACU (OAA/S: 0-5)	3.4 ± 0.9	3.1 ± 0.5
Sedation Score at Discharge from PACU (OAA/S: 0-5)	4.6 ± 0.5	5.0 ± 0.2 *
Anesthesia time, min	69.5 ± 35.7	72.8 ± 27.9
Time in PACU, min	62.0 ± 43.1	58.9 ± 35.0

Data are reported as mean ± standard deviation. * $P<0.05$.

ANOVA with repeated measures for sedation scores showed a significant time effect but no significant group effect (time $F=125.10$, $P<.0001$, Group $F=.30$, $P<.59$). Independent t -tests performed at each time point for pain and sedation scores, detected a significant difference between groups for sedation at PACU discharge only. The LAV patients were significantly less sedated than the patients in the PL group (4.6 vs 5.0, $t=3.19$, $P=.003$).

There was a statistically significant difference in the total amount of morphine consumed postoperatively between groups; the LAV patients required less morphine (2.38 mg vs 4.26 mg, $t=2.16$, $P<.04$). Moreover, significantly more patients in the PL group required opioid treatment for postoperative pain (22/27, 82%) than LAV patients (12/26, 46%) (Chi-square = 7.2, $P=.007$). There were no differences in the requirements for postoperative antiemetics (in addition to ondansetron) or antihypertensives (Table 2).

Discussion

Our study showed that lavender aromatherapy administered in the immediate postoperative period to patients undergoing laparoscopic intraabdominal surgery, decreases the need for postoperative opioids. In addition, the lavender oil appears to have a positive

effect on sedation levels, with the LAV patients being less sedated upon discharge from the PACU. However, difference in sedation levels did not affect the discharge time. There was no statistical difference in pain score. The results of this study support previous work that indicates that aromatherapy has a positive effect on the subjective experience of pain.⁸

The mechanism of pain after laparoscopic procedures is multifactorial, with stimuli arising from the incision sites, pneumoperitoneum, and diaphragmatic irritation from fluid. Incisional pain typically can be managed by opioid analgesics, which have no ceiling in their analgesic effect. Their efficacy, however, is often limited by their tolerability profile and poor control of visceral pain. The multiplicity of mechanisms involved in pain suggests that a combination of opioid and non-opioid drugs would improve postoperative analgesia, as well as reduce the opioid requirements and associated side-effects. Indeed, "multimodal" or "balanced analgesia" is advocated as a preferred method to treat postoperative pain.^{3,4} Ketorolac, the only parenteral NSAID available in the United States, is routinely used in patients undergoing LAGB in our institution. It is well documented that an addition of NSAIDs reduces opioid consumption by approximately 30%.^{9,10} NSAIDs are specifically recommended for the treatment of visceral pain, which may be caused by inflammatory mediators.¹¹ Ketorolac, however, can interfere with platelet function, the repair of gastric and intestinal mucosa, and maintenance of renal tubular blood-flow. These side-effects limit its use in high risk patients. Some authors discourage use of NSAIDs after bariatric procedures.¹² Although none of our patients developed NSAID-associated side-effects, we did not administer ketorolac to 6 patients with severe gastroesophageal reflux (two in PL and four in LAV). Given the above considerations, the addition of newer methods for postoperative analgesia could further reduce postoperative stress, increase safety, and enhance comfort in patients undergoing LAGB.

The use of complimentary non-pharmacologic treatments as an adjunctive therapy for management of postoperative pain may decrease the requirements for traditional analgesics, hence reducing the incidence of adverse effects. A variety of nonpharmacological therapies (i.e. acupuncture, transcutaneous electrical nerve stimulation, music, relaxation tech-

Table 2. Perioperative medications

	Placebo Group N = 27	Lavender Group N = 26
Fentanyl, mcg (intraoperative)	276 ± 124	253 ± 141
Trimethobenzamide in PACU (n, %)	3, 11.1	2, 7.8
Fimotidine in PACU (n, %)	5, 18.5	3, 11.5
Labetalol in PACU (n, %)	3, 11.1	4, 15.3
Hydralazine in PACU (n, %)	2, 7.4	3, 11.5
Metoprolol in PACU (n, %)	0, 0	1, 3.8

N = total number of patients in the treatment group. n = number of patients who were treated with a particular drug.

niques) have been tested for reduction of postoperative pain and/or analgesic requirements. Use of essential oils is one of the fastest growing complimentary therapies.¹³ Numerous reports showed the usefulness of essential oils in various clinical settings.¹⁴

Pain is a subjective sensation, which includes physical stimulus, as well as motivational and affective components. It is perceived in the context of cultural factors, previous experiences, anxiety and depression. Thus, it is difficult to analyze the role of a particular mechanism on the overall experience. Aromatherapy consistently produces a psychological improvement in mood and anxiety levels,¹⁵ as well as a reduction in sympathetic stimulation.¹⁶ Lavender treatment has produced significant antinociception in the animal model.¹⁷ Clinical trials have documented that essential oils may alleviate anxiety of pain and promote relaxation in hospital settings.^{14,18} However, the exact mechanism of pain reduction (or perception of it) associated with aromatherapy remains elusive. There is a paucity of data on the use of aromatherapy for postoperative pain control. Our recent pilot study on the use of aromatherapy for the treatment of postoperative pain after breast biopsy showed that patients treated with lavender oil reported a higher satisfaction rate with pain control.⁸ A difference in narcotic requirements did not reach statistical significance, possibly due to small sample size and a low intensity of pain associated with breast biopsy (which reduces discriminating power). The current trial was carefully designed to reduce the shortcomings of our previous investigation. We choose LABG for the following reasons: a) uniformity of the surgical approach which leads to similar requirements for postoperative analgesia; b) significant visceral pain which is poorly responsive to opioids; and c) importance of reducing opioid associated adverse effects in the morbidly obese patients. It is the first study showing that aromatherapy directly affects the perceived intensity of pain, thus reducing demand for analgesics.

Although the use of multimodal pain management strategies reduces opioid consumption, improvements in analgesic efficacy and reduction of side-effects are observed less often.^{9,19} We, likewise, were unable to demonstrate a decrease in the incidence of postoperative nausea or PACU discharge time. A statistically significant difference in sedation scores on discharge did not translate into a clinically

relevant outcome. All our patients were pre-treated with ondansetron. This therapy would explain the low requirements for additional antiemetics. Patients in both groups had similar discharge times. Treatment of pain is only one of the many factors (including administrative and logistical) that affect the length of stay in the PACU. Thus, it is not surprising that we did not observe a difference in this outcome.

Our study has several limitations. First, the placebo effect cannot be ignored. The use of real placebo is difficult because of the perfume of essential oil. It is possible that any aroma (not just lavender oil) may have a positive effect on pain perception. In addition, the fact that informed consent is required from a participant, may pre-select a subset of patients who were more open-minded about the possible beneficial effects of complementary therapies. Second, we did not measure levels of either essential oils constituents in plasma or stress hormones (or other physiological changes) induced by pain. There are two mechanisms that may explain the positive effect of essential oils: pharmac-physiologic and psycho-physiologic. The constituents of essential oils may act on cellular receptors if a sufficient quantity of the agent reaches the central nervous system structures via the olfactory bulb, or is carried by blood (absorbed through the lung or nasal mucosa). On the other hand, pleasantness of the lavender smell may alter physiological reaction to pain by affecting an "emotional" response. Although our study demonstrates that lavender oil reduces postoperative analgesic requirements, we cannot comment on the mechanism of this effect without further experiments. Third, we did not evaluate the patient's anxiety or personality-type preoperatively. These assessments might be important in an evaluation of the therapy which is based on reducing psychological response to stress.

In conclusion, we conducted a prospective, open-label, placebo-controlled clinical trial that tested the effects of lavender aromatherapy in reducing postoperative pain and opioid demand in patients undergoing laparoscopic gastric banding. Our study showed reduction in opioid consumption after postoperative lavender aromatherapy. The study did not have a sufficient power to detect the difference in clinical outcomes (i.e. PACU discharge time, incidence of respiratory complications, etc.). The effec-

tiveness of the aromatherapy treatment in reducing postoperative perception of pain without evidence of adverse effects, supports the interest for potential use of aromatherapy in perioperative care.

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(Received March 6, 2007; accepted April 17, 2007)